

# EXHIBIT N

Vladimir Iakovlev, M.D.

Page 1

CAUSE NO. 2012-CI-18690

JENNIFER RAMIREZ F/K/A ) IN THE DISTRICT COURT

JENNIFER GALINDO, )

Plaintiff,)

v. ) 438th JUDICIAL DISTRICT

CESAR REYES, M.D., )

JOHNSON & JOHNSON, )

AND ETHICON, INC., )

Defendant. ) BEXAR COUNTY, TEXAS

-----)

--- This is the Videotaped Deposition of VLADIMIR  
IAKOVLEV, M.D., taken at the Hilton Hotel,  
University Room, 145 Richmond Street West,  
Toronto, Ontario, on the 19th day of April, 2016.

-----

REPORTED BY: HELEN MARTINEAU

CERTIFIED SHORTHAND REPORTER

VIDEOGRAPHER: DAVID LANE

Vladimir Iakovlev, M.D.

Page 2	Page 4
<p>1 A P P E A R A N C E S:</p> <p>2 FOR THE PLAINTIFF AND THE WITNESS:</p> <p>3 ANDERSON LAW OFFICE , LLC</p> <p>4 BENJAMIN H. ANDERSON, ESQ.</p> <p>5 1360 West 9th Street, Suite 215</p> <p>6 Cleveland, Ohio 44113</p> <p>7 Tel. 216.589.0256</p> <p>8 Email: ben@andersonlawoffices.net</p> <p>9</p> <p>10 FOR THE PLAINTIFF AND THE WITNESS:</p> <p>11 FREESE AND GOSS</p> <p>12 RICH FREESE, ESQ.</p> <p>13 1901 6th Avenue North, Suite 3120</p> <p>14 Birmingham, AL 35203</p> <p>15 Tel. 205.871.4144</p> <p>16 Email: rich@freeseandgoss.com</p> <p>17</p> <p>18 FOR THE DEFENDANT:</p> <p>19 BUTLER SNOW, LLP</p> <p>20 CHAD R. HUTCHINSON, ESQ.</p> <p>21 1020 Highland Colony Parkway, Suite 1400</p> <p>22 Ridgeland, MS 39157</p> <p>23 Tel. 601.985.4401</p> <p>24 Email: Chad.hutchinson@butlersnow.com</p>	<p>1 INDEX OF WITNESSES</p> <p>2 WITNESS: PAGE</p> <p>3 VLADIMIR IAKOVLEV, MD, Affirmed</p> <p>4 DIRECT EXAMINATION BY MR. ANDERSON.....9</p> <p>5 CROSS-EXAMINATION BY MR. HUTCHINSON.....153</p> <p>6 RE-DIRECT EXAMINATION BY MR. ANDERSON.....359</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>
Page 3	Page 5
<p>1 A P P E A R A N C E S: (continued)</p> <p>2 FOR THE DEFENDANT REYES:</p> <p>3 SCOTT, CLAWATER &amp; HOUSTON, L.L.P.</p> <p>4 CAROL Y. VERBEEK, ESQ. (via Skype call)</p> <p>5 2727 Allen Parkway, Suite 500</p> <p>6 Houston, TX 77019</p> <p>7 Tel. 713.650.6600</p> <p>8 Email: cverbeek@schlawyers.com</p> <p>9</p> <p>10 FOR THE DEFENDANT:</p> <p>11 THOMAS COMBS &amp; SPANN, PLLC</p> <p>12 PHILIP J. COMBS, ESQ.</p> <p>13 300 Summers Street, Suite 1380</p> <p>14 Charleston, WV 25301</p> <p>15 Tel. 304.414.1805</p> <p>16 Email: pcombs@tcspllc.com</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 INDEX OF EXHIBITS</p> <p>2 NO./ DESCRIPTION PAGE</p> <p>3 PLAINTIFF'S EXHIBITS</p> <p>4 1 Curriculum vitae of Vladimir Iakovlev, 13</p> <p>5 MD, prepared March 18, 2016.</p> <p>6 2 Brochure for the Bard Davol Inc. 23</p> <p>7 European Hernia Symposium, Berlin,</p> <p>8 Germany, 2015.</p> <p>9 3 Pathology report from UT Southwestern 41</p> <p>10 Medical Center re. Jennifer Ramirez,</p> <p>11 printed 4/1/2015.</p> <p>12 4(A) to 4(M) Series of photographs taken by 50</p> <p>13 Dr. Iakovlev during the examination of</p> <p>14 Jennifer Ramirez's specimen.</p> <p>15 5 Diagram depicting the spinal cord. 70</p> <p>16 6 Diagram prepared by Dr. Iakovlev 75</p> <p>17 depicting the relationship of the</p> <p>18 excised pieces to the anatomical</p> <p>19 structures in Ms. Jennifer Ramirez's</p> <p>20 body.</p> <p>21 7(A) to 7(D) Series of high magnification 80</p> <p>22 images depicting the specimen from Mr.</p> <p>23 Ramirez excised in March 2015.</p> <p>24 8 Article titled "Comparison of the In 90</p> <p>Vivo Behavior of Polyvinylidene</p> <p>Fluoride and Polypropylene Sutures</p> <p>Used in Vascular Surgery", found in</p> <p>OSAIO Journal 1998. Bates labelled</p> <p>ETH.MESH.05845592 to ETH.MESH05845599.</p> <p>9 Article titled "Structural alterations 91</p> <p>of prosthetic meshes in humans" found</p> <p>in Hernia Journal, 2003.</p> <p>10 Article titled "Materials 92</p> <p>Characterization of Explanted</p> <p>Polypropylene Hernia Meshes" found in</p> <p>the Journal of Biomedical Materials</p> <p>Research Part B: Applied Biomaterials.</p> <p>11 Article titled "Materials 94</p> <p>characterization of explanted</p> <p>polypropylene, polyethylene</p> <p>terephthalate, and expanded</p> <p>polytetrafluoroethylene composites:</p> <p>Spectral and thermal analysis", found</p> <p>in Journal of Biomedical Materials</p>

2 (Pages 2 to 5)

## Vladimir Iakovlev, M.D.

Page 6	Page 8
<p>1 Research Part B: Applied Biomaterials.</p> <p>2</p> <p>3 12 Article titled "Physical 95</p> <p>4 Characteristics of Medical Textile</p> <p>5 Prostheses Designed for Hernia Repair:</p> <p>6 A Comprehensive Analysis of Select</p> <p>7 Commercial Devices", found in MDPI</p> <p>8 Materials, 2015.</p> <p>9 13 Article titled "Degradation of 97</p> <p>10 polypropylene in the human eye: A</p> <p>11 sem-study", found in Documenta</p> <p>12 Ophthalmologica, 1986.</p> <p>13 14 Article titled "Reinforcement 98</p> <p>14 Materials in Soft Tissue Repair: Key</p> <p>15 Parameters Controlling Tolerance and</p> <p>16 Performance - Current and Future</p> <p>17 Trends in Mesh Development", found in</p> <p>18 the journal New Techniques in Genital</p> <p>19 Prolapse Surgery, 2011.</p> <p>20 15 Article titled "Subcutaneous Implants 100</p> <p>21 of Polypropylene Filaments", found in</p> <p>22 the Journal of Biomedical Material</p> <p>23 Research, 1976.</p> <p>24 16 Article titled "Degradation, infection 101</p> <p>and heat effects on polypropylene mesh</p> <p>for pelvic implantation: what was</p> <p>known and when it was known", found in</p> <p>the International Urogynecology</p> <p>Journal, 2011.</p> <p>17 17 Article titled "Post-Implantation 102</p> <p>18 alterations of Polypropylene in the</p> <p>19 Human", found in The Journal of</p> <p>20 Urology, 2012.</p> <p>21 18 Article titled "Materials 104</p> <p>22 characterization and histological</p> <p>23 analysis of explanted polypropylene,</p> <p>24 PTFE, and PET hernia meshes from an</p> <p>individual patient", found in the</p> <p>Journal of Material Medicine, 2013.</p> <p>19 Article titled "Pathology of Explanted 105</p> <p>Transvaginal Meshes", found in World</p> <p>Academy of Science, Engineering and</p> <p>Technology International Journal of</p> <p>Medical, Health, Pharmaceutical and</p> <p>Biomedical Engineering, 2014.</p>	<p>1 Ramirez dated 10/5/2015.</p> <p>2</p> <p>3 5 Diagram depicting the female anatomy 201</p> <p>4 after a hysterectomy is done.</p> <p>5 6 Diagram depicting the muscles in the 205</p> <p>6 female pelvic floor.</p> <p>7 7 Article titled "Histopathology of 209</p> <p>8 excised midurethral sling mesh", found</p> <p>9 in the International Urogynecology</p> <p>10 Journal, 2015.</p> <p>11 8 Document titled "TR-19/2007 Chemical 240</p> <p>12 Resistance of Thermoplastics Piping</p> <p>13 Materials" from the Plastics-Pipe</p> <p>14 Institute, dated September 2007.</p> <p>15 9 Rule 26 expert report of Dr. Vladimir 310</p> <p>16 Iakovlev re. Jo Husky, et al., and</p> <p>17 Tonya Edwards, et al.</p> <p>18 10 Addendum to the Rule 26 expert report 313</p> <p>19 of Dr. Vladimir Iakovlev re.</p> <p>20 Lisa Marie Fontes, et al.</p> <p>21 11 Rule 26 expert report of Vladimir 320</p> <p>22 Iakovlev, re. Diane Bellew.</p> <p>23 12 Rule 26 expert report of Dr. Vladimir 324</p> <p>24 Iakovlev re. Amal Eghnayem.</p> <p>13 Report by Dr. Iakovlev titled 336</p> <p>"Clinico-pathological Correlation of</p> <p>Complications Experienced by Ms.</p> <p>Virginia White".</p> <p>14 Medical report from Mercy Hospital 338</p> <p>15 Northwest Arkansas re. Virginia White.</p> <p>16 Bates labelled WHITEV_SMAMM_MDR00027.</p> <p>17 Expert report of Dr. Iakovlev In Re. 351</p> <p>18 Ethicon, Inc., Pelvic Repair System</p> <p>19 Products Liability Litigation relating</p> <p>20 to all Wave 1 Cases.</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>
Page 7	Page 9
<p>1 INDEX OF EXHIBITS</p> <p>2 NO./ DESCRIPTION PAGE</p> <p>3 20 Article titled, "Degradation of 107</p> <p>4 polypropylene in vivo: A microscopic</p> <p>5 analysis of meshes explanted from</p> <p>6 patients", found in the Journal of</p> <p>7 Biomedical Materials Part B, 2015.</p> <p>8 21 Printout of PowerPoint slides created 110</p> <p>9 with the assistance of Dr. Iakovlev</p> <p>10 for presentation to the jury.</p> <p>11 22 Article titled "Pathologic Evaluation 124</p> <p>12 of Explanted Vaginal Mesh:</p> <p>13 Interdisciplinary Experience From a</p> <p>14 Referral Center", found in the Journal</p> <p>15 of Female Pelvic Medicine &amp;</p> <p>16 Reconstructive Surgery, 2013.</p> <p>17 23 Internal Ethicon Research Foundation 130</p> <p>18 document dated March 23, 1983. Bates</p> <p>19 labelled ETH.MESH.15955438 to</p> <p>20 ETH.MESH.15955439.</p> <p>21 24 Internal document from Ethicon 135</p> <p>22 Research Foundation dated May 2, 1984.</p> <p>23 Bates labelled ETH.MESH.15955462 to</p> <p>24 ETH.MESH.15955468.</p> <p>25 Two pages depicting high magnification 143</p> <p>images for comparison.</p> <p>16 DEFENSE EXHIBITS:</p> <p>17</p> <p>18 1 Expert report of Dr. Vladimir Iakovlev 167</p> <p>19 re. Jennifer Ramirez, dated April 24,</p> <p>20 2015.</p> <p>21 2 Medical report from Baptist Health 172</p> <p>22 System re. Jennifer Galindo dated</p> <p>23 1/21/2015. Bates labelled</p> <p>24 RAMIREZJ_BAHSY_MDR00564.</p> <p>3 Patient record from UT Southwestern 184</p> <p>Medical Center re. Jennifer Ramirez,</p> <p>printed on 4/6/2015. Bates labelled</p> <p>RAMIREZJ_UTSMC_MDR00311.</p> <p>4 Surgical pathology report from St. 186</p> <p>Michael's Hospital re. Jennifer</p>	<p>1 --- Upon commencing at 9:15 a.m.</p> <p>2 THE VIDEOGRAPHER: My name is David Lane</p> <p>3 I'm the videographer for Golkow Technologies.</p> <p>4 Today's date is April 19th, 2016. Our time is</p> <p>5 9:15 a.m. This deposition is taking place in</p> <p>6 Toronto, Ontario, in the matter of Jennifer</p> <p>7 Ramirez versus Ethicon Inc. et al. Our deponent</p> <p>8 today is Dr. Vladimir Iakovlev, MD. Our deponent</p> <p>9 -- counsel will be noted on the stenographic</p> <p>10 record. Our court reporter today is Helen</p> <p>11 Martineau. Would the court reporter please swear</p> <p>12 in the witness.</p> <p>13 (WHEREUPON, the witness was duly affirmed.)</p> <p>14 VLADIMIR IAKOVLEV, M.D.,</p> <p>15 called as a witness herein,</p> <p>16 having been first duly sworn,</p> <p>17 was examined and testified as follows:</p> <p>18 DIRECT EXAMINATION BY MR. ANDERSON:</p> <p>19 Q. Good morning.</p> <p>20 A. Good morning.</p> <p>21 Q. What is your name?</p> <p>22 A. Vladimir Iakovlev.</p> <p>23 Q. What is your occupation?</p> <p>24 A. I'm a doctor and I'm a pathologist.</p>

3 (Pages 6 to 9)

Vladimir Iakovlev, M.D.

Page 10	Page 12
<p>1 Q. What is pathology?</p> <p>2 A. Pathology is part of medicine is</p> <p>3 laboratory medicine. Pathologists are doctors who</p> <p>4 work in the lab in the hospital. We receive</p> <p>5 samples from the patients the samples are taken by</p> <p>6 the treating doctors. Samples would be fluids</p> <p>7 like blood and urine, or tissue samples like</p> <p>8 biopsies from tumors or larger organs resected</p> <p>9 from the body. We analyze them, we cannot do all</p> <p>10 possible tests so we do only those tests which are</p> <p>11 needed to manage the patient immediately. We</p> <p>12 report these results to the commissions or to</p> <p>13 treating doctors and they treat the patients.</p> <p>14 Q. Do you have a particular focus</p> <p>15 within pathology?</p> <p>16 A. I am an anatomical pathologist.</p> <p>17 Q. And what is an anatomical</p> <p>18 pathologist?</p> <p>19 A. Anatomical pathology is part of</p> <p>20 pathology where laboratory doctors examine tissue</p> <p>21 samples not fluids like blood but tissue sample,</p> <p>22 scrapings of cells like pap smears, or biopsy from</p> <p>23 tumors like a core biopsy from a breast lump, or</p> <p>24 larger resections like part of bowel or lump from</p>	<p>1 number. But then at certain point they need our</p> <p>2 help. So they take samples like blood or the</p> <p>3 tissue samples and send it to the laboratory. And</p> <p>4 then laboratory doctors like me examine these</p> <p>5 specimens and we work down the pathological part</p> <p>6 of the differential diagnosis. We narrow down</p> <p>7 that list to one disease which caused the</p> <p>8 symptoms.</p> <p>9 Q. So is the differential diagnosis</p> <p>10 that you perform as a pathologist the same or</p> <p>11 different as a differential diagnosis by patient's</p> <p>12 treating doctor or clinician?</p> <p>13 A. It's the same and it's different.</p> <p>14 Q. Okay. Please explain?</p> <p>15 A. It's a part of the larger</p> <p>16 differential diagnosis because treating doctors</p> <p>17 can narrow it down to a certain point but they</p> <p>18 still need our help otherwise we wouldn't be</p> <p>19 needed in the hospital, we wouldn't have a job.</p> <p>20 But at certain point they have to take biopsies</p> <p>21 and send it to us and then we can do our</p> <p>22 pathological differential diagnosis or we can rule</p> <p>23 out diseases which can be ruled out only by using</p> <p>24 a microscope not by just examining the patient.</p>
Page 11	Page 13
<p>1 the breast, or sometimes we examine the entire</p> <p>2 body. We do an autopsy. You probably have seen</p> <p>3 autopsies on TV.</p> <p>4 Q. You said the word "resection", what</p> <p>5 is a resection?</p> <p>6 A. Resection is when a part of the</p> <p>7 organ is cut-out. Resected means cut out. It can</p> <p>8 be an organ or it can be a part of device like a</p> <p>9 mesh.</p> <p>10 Q. Are you familiar with a term in</p> <p>11 medicine known as "differential diagnosis"?</p> <p>12 A. Yes, I am.</p> <p>13 Q. Is that something that you as an</p> <p>14 anatomical pathologist use in your daily practice?</p> <p>15 A. Yes, I do.</p> <p>16 Q. Can you please explain for the jury</p> <p>17 what a differential diagnosis is?</p> <p>18 A. A differential diagnosis is a list</p> <p>19 of possible diseases which can cause similar</p> <p>20 symptoms. When the patient comes in they report</p> <p>21 specific symptoms so the treating doctor has a</p> <p>22 list of possible diseases which can cause the</p> <p>23 symptoms. They take the history, they examine the</p> <p>24 patient then they narrow down that list to smaller</p>	<p>1 Q. And is this the process that you've</p> <p>2 described that you do every day in your daily</p> <p>3 practice what you did in this case in arriving at</p> <p>4 your expert conclusions in Ms. -- for Ms. Ramirez?</p> <p>5 A. That's correct. I use exactly the</p> <p>6 same approach for examining Ms. Ramirez's specimen</p> <p>7 as I do in my routine, day-to-day practice.</p> <p>8 Q. Okay. Showing you what we have</p> <p>9 marked for identification as Exhibit 1.</p> <p>10 ---PLAINTIFF EXHIBIT NO. 1: Curriculum</p> <p>11 vitae of Vladimir Iakovlev, MD,</p> <p>12 prepared March 18, 2016.</p> <p>13 BY MR. ANDERSON:</p> <p>14 Q. First can you please identify this</p> <p>15 for the record?</p> <p>16 A. This is my curriculum vitae.</p> <p>17 Q. AND what is a curriculum vitae?</p> <p>18 A. It's a document which describes all</p> <p>19 my career, my education, my licenses, my</p> <p>20 publications, my teaching.</p> <p>21 Q. And you have it there in front of</p> <p>22 you if you need to refer to it at any time. I</p> <p>23 just want to go through with the jury a bit of</p> <p>24 your background education and employment history,</p>

4 (Pages 10 to 13)

Vladimir Iakovlev, M.D.

Page 14	Page 16
<p>1 okay?</p> <p>2 A. Okay.</p> <p>3 Q. Where do you currently work?</p> <p>4 A. I work at St. Michael's Hospital,</p> <p>5 Toronto, Canada.</p> <p>6 Q. What is your current position?</p> <p>7 A. I'm a pathologist and I'm also a</p> <p>8 director of cytopathology at St. Michael's</p> <p>9 Hospital.</p> <p>10 Q. Okay, that's a new word. What is</p> <p>11 cytopathology?</p> <p>12 A. Cytopathology is part of anatomical</p> <p>13 pathology but I'm focusing more on smaller</p> <p>14 samples. When the samples are sucked out through</p> <p>15 a fine needle or they are scraped.</p> <p>16 Q. And how long have you been at St.</p> <p>17 Michael's?</p> <p>18 A. About nine years.</p> <p>19 Q. Explain to the jury what you do,</p> <p>20 Doctor, on a day-to-day basis at St. Michael as an</p> <p>21 anatomic pathologist?</p> <p>22 A. As an anatomic pathologist, or as</p> <p>23 any pathologist we receive specimens. These</p> <p>24 specimens are taken out by treating doctors or by</p>	<p>1 them in the microscope and then we describe it.</p> <p>2 We go through morphological differential or</p> <p>3 pathological differential diagnosis and we make a</p> <p>4 diagnosis and report it to the treating doctors.</p> <p>5 Q. Are you familiar with the term</p> <p>6 clinico-pathological correlation?</p> <p>7 A. Yes, I am.</p> <p>8 Q. Can you explain what that means to</p> <p>9 you as a pathologist this word</p> <p>10 clinico-pathological correlation?</p> <p>11 A. This is like putting different</p> <p>12 pieces of information together, like species in</p> <p>13 jigsaw puzzle. As I explain or as I described</p> <p>14 when the patient comes in treating doctors examine</p> <p>15 the patient, take history, so they collect some</p> <p>16 pieces of information.</p> <p>17 Then when I receive it I also see what</p> <p>18 radiologist were reporting or describing by using</p> <p>19 X-rays or CT scans and then I examine the</p> <p>20 specimen. So I have my pieces of information.</p> <p>21 When I put everything together then we can arrive</p> <p>22 to the correct diagnosis. And this is called</p> <p>23 "clinico-pathological correlation", when we</p> <p>24 correlate all of the pieces of information from</p>
Page 15	Page 17
<p>1 radiologist. So they take a biopsy or they resect</p> <p>2 an organ and they send it to the lab. In the lab</p> <p>3 we receive the specimen; we make sure that it</p> <p>4 belongs to correct patient; we make sure that</p> <p>5 everything is labelled correctly; and then we</p> <p>6 examine this specimen or part of the body which</p> <p>7 was resected, or biopsy. We describe it grossly</p> <p>8 how it looks, how it feels by fingers. We cut</p> <p>9 through it, look inside, how it looks inside and</p> <p>10 then we decide how to take sections for</p> <p>11 microscopic examination.</p> <p>12 Q. When you say "sections" what do you</p> <p>13 mean?</p> <p>14 A. Sections when we slice it like a</p> <p>15 bread through or we call it cross-sectioning, it's</p> <p>16 like slicing bread. And then when we slice it we</p> <p>17 can look inside and see what's inside. And then</p> <p>18 we can take these slices and put them in the</p> <p>19 microscope, shine light through and see what is in</p> <p>20 the tissue.</p> <p>21 So after we slice it with scalpel then</p> <p>22 we submit it to make histological slides. And</p> <p>23 then the lab makes histological slides, slides</p> <p>24 like this, and then we use a microscope to examine</p>	<p>1 clinical treating physicians, treating doctors to</p> <p>2 pathology information.</p> <p>3 Q. So please briefly describe for the</p> <p>4 jury your education and training that prepared you</p> <p>5 to work as a pathologist.</p> <p>6 A. A pathologist needs to go first</p> <p>7 through medical school. My medical school</p> <p>8 training was in Russia. At that time system in</p> <p>9 Russia was similar to United Kingdom. If people</p> <p>10 do well, they have good grades in high school they</p> <p>11 can be accepted in medical school straight out of</p> <p>12 high school. I had good grades; I volunteer in</p> <p>13 the ward; I attended some scientific society when</p> <p>14 I was in high school; and I was accepted straight</p> <p>15 from high school.</p> <p>16 Q. And you say you volunteered at the</p> <p>17 ward. Is that volunteering at the ward of a</p> <p>18 hospital?</p> <p>19 A. Yes.</p> <p>20 Q. Go ahead, I'm sorry.</p> <p>21 A. But you -- some people do first</p> <p>22 degree, bachelor degree and then they apply to</p> <p>23 medical school like here in North America so there</p> <p>24 are two ways, but if you have good grades and show</p>

5 (Pages 14 to 17)

Vladimir Iakovlev, M.D.

Page 18	Page 20
<p>1 your dedication you can be accepted straight from 2 high school.</p> <p>3 When I completed high school it was a 4 time of great struggle in Russia, it was '90s. 5 The government didn't have enough money and they 6 couldn't invest into medical care. My wife and I 7 decided to move at that time and we came to 8 Canada. We took Canadian and American licensing 9 exams and then we continued our training as 10 anatomical pathologists here.</p> <p>11 After I completed the residency then I 12 applied for research fellowship at Ontario Cancer 13 Institute. That is here in Toronto. This is the 14 largest cancer institute in Canada. And when I 15 completed it I had an offer from St. Michael's 16 Hospital and I was also appointed at the 17 University of Toronto.</p> <p>18 Q. Where do you hold medical licenses? 19 A. I hold medical license in the 20 Province of Ontario, Canada, and the State of 21 Michigan, United States.</p> <p>22 Q. Are you Board certified in any 23 fields? 24 A. I'm Board certified in anatomical</p>	<p>1 the American Board of Pathology and Royal College 2 of Physicians of Canada. This stimulates you to 3 study and update your knowledge yearly.</p> <p>4 Q. Are you currently a member of any 5 professional societies in your field? 6 A. Yes. I am Fellow of the Royal 7 College of Physicians of Canada and College of 8 American Pathologists.</p> <p>9 Q. Do you currently have any teaching 10 responsibilities? 11 A. Yes. I teach medical students. I 12 teach residents, pathology residents and residents 13 from other specialties. I teach 14 cytotechnologists, physiotherapists and 15 pathologists.</p> <p>16 Q. What do you teaching duties entail? 17 A. For residents and fellow I teach 18 them practice of pathology how we do it 19 day-by-day; for cytotechnologists it's a more of a 20 formal sessions; for pathologists I do courses at 21 conferences and teach them the field of 22 cytopathology because I'm more focused on 23 cytopathology.</p> <p>24 Q. Are those principles of differential</p>
Page 19	Page 21
<p>1 pathology by the Royal College of Physicians and 2 Surgeons of Canada, and by the Canadian -- 3 American Board of Pathology.</p> <p>4 Q. Real briefly how does one obtain 5 Board certification? 6 A. Board certification is obtained by 7 submitting all your education, training, and 8 experience. If it is found to be acceptable they 9 will allow you to sit the exam. You sit the exam 10 and if you are successful you obtain Board 11 certification.</p> <p>12 Q. And do you have to retake the Board 13 certification exam? 14 A. Yes. This was a new approach lately 15 because the field of pathology is changing so fast 16 those pathologists who are not updating their 17 knowledge couldn't deliver the same standard of 18 care. So now the rule is to retake the certifying 19 exam every ten years. And I retook it last year, 20 it was a ten-year mark for me.</p> <p>21 Q. As a current practicing pathologist 22 are you required to complete continuing medical 23 education courses in your field? 24 A. Yes, this is another initiative by</p>	<p>1 diagnosis and clinico-pathological correlation 2 that you just described for the jury a few minutes 3 ago, are those things that you teach to your 4 students as well as your fellows and your 5 residents?</p> <p>6 A. Yes, because these are basic 7 principles. That's how we arrive to the correct 8 diagnosis.</p> <p>9 Q. And did you apply those principles 10 in forming your expert conclusions that you'll be 11 presenting to the Court and the jury today? 12 A. Yes, I did.</p> <p>13 Q. Have you written articles that have 14 been publish in the scientific literature? 15 A. Yes. I published over 20 full-size 16 articles and over 30 abstracts, I also presented 17 at multiple international meetings.</p> <p>18 Q. Do any of those articles or 19 abstracts relate to your examination of explanted 20 surgical meshes made out of polypropylene like the 21 TVT-O sling device that is the subject of this 22 trial? 23 A. Yes. 24 Q. How many?</p>

6 (Pages 18 to 21)



Vladimir Iakovlev, M.D.

Page 22	Page 24
<p>1 A. I published five papers, five</p> <p>2 articles on this subject and over ten abstracts on</p> <p>3 this subject of implantable meshes. Also I</p> <p>4 presented -- I was invited to present at multiple</p> <p>5 international scientific meetings.</p> <p>6 Q. Has your research included</p> <p>7 publications in the peer-reviewed literature on</p> <p>8 the topics of, and I'll make a list, the pathology</p> <p>9 of surgical meshes like TVT-O?</p> <p>10 A. That's correct.</p> <p>11 Q. Microscopic analysis of the changes</p> <p>12 in the tissue when the mesh is implanted in the</p> <p>13 body?</p> <p>14 A. That's correct.</p> <p>15 Q. Correlation of your microscopic</p> <p>16 pathological findings to the mesh patients'</p> <p>17 medical problems that led to surgical removal of</p> <p>18 the mesh?</p> <p>19 A. That's correct.</p> <p>20 Q. Microscopic analysis of the</p> <p>21 degradation of polypropylene mesh in the human</p> <p>22 body including degradation of the TVT-O device?</p> <p>23 A. Yes, I did.</p> <p>24 Q. Have you ever been invited by a</p>	<p>1 A. Yes, this is the program of the</p> <p>2 meeting.</p> <p>3 Q. And can you please pull that up? If</p> <p>4 you could blow up the top.</p> <p>5 You mentioned the company Bard, is the</p> <p>6 company that invited you to speak at this</p> <p>7 international conference?</p> <p>8 A. Yes, it is.</p> <p>9 Q. Were there mesh scientists from</p> <p>10 around the world at this conference?</p> <p>11 A. Yes, there were.</p> <p>12 Q. Including scientists and consultants</p> <p>13 from Bard?</p> <p>14 A. Yes.</p> <p>15 Q. Including scientists and consultants</p> <p>16 from Ethicon?</p> <p>17 A. Yes.</p> <p>18 Q. Did you interact with many of these</p> <p>19 scientists and consultants at the conference?</p> <p>20 A. Yes, I did.</p> <p>21 Q. Have you spoken at other</p> <p>22 international conferences about your research and</p> <p>23 the topics you'll be presenting to the jury here</p> <p>24 today?</p>
Page 23	Page 25
<p>1 medical device company to speak at one of their</p> <p>2 conferences about polypropylene mesh products like</p> <p>3 the TVT-O?</p> <p>4 A. Yes, I was invited to one of these</p> <p>5 conferences.</p> <p>6 Q. And where was that?</p> <p>7 A. There was an annual hernia repair</p> <p>8 conference in Berlin.</p> <p>9 Q. When was that?</p> <p>10 A. It was in September last year.</p> <p>11 Q. Who invited you to speak at that</p> <p>12 conference?</p> <p>13 A. It was a scientific committee of</p> <p>14 Bard. Bard is a similar manufacturer like Ethicon</p> <p>15 or competitor of Ethicon manufacturing implantable</p> <p>16 meshes.</p> <p>17 Q. I'm showing you what we have marked</p> <p>18 as Exhibit 2.</p> <p>19 ---PLAINTIFF EXHIBIT NO. 2: Brochure</p> <p>20 for the Bard Davol Inc. European Hernia</p> <p>21 Symposium, Berlin, Germany, 2015.</p> <p>22 BY MR. ANDERSON:</p> <p>23 Q. Can you please identify that for the</p> <p>24 record?</p>	<p>1 A. Yes, I did.</p> <p>2 Q. If we could go to the next page.</p> <p>3 Highlight the top. You asked me to highlight some</p> <p>4 of the names here. Are you familiar with these</p> <p>5 names?</p> <p>6 A. Um, these are co-authors of some</p> <p>7 research articles we published together and my</p> <p>8 name. You can see my name.</p> <p>9 Q. If you can highlight the part of the</p> <p>10 agenda where he spoke.</p> <p>11 What topic were you invited to speak on</p> <p>12 at this international conference?</p> <p>13 A. This was a topic of pro's and con's</p> <p>14 of surgery with mesh versus without mesh.</p> <p>15 Q. Okay. Either at this mesh</p> <p>16 conference, or at any of the international</p> <p>17 conferences were you have presented your</p> <p>18 scientific work on mesh, did any scientist, or</p> <p>19 employee, or executive of any mesh manufacturer</p> <p>20 ever stand up at the conference or come up to you</p> <p>21 at any point and question you regarding your</p> <p>22 credentials?</p> <p>23 MR. HUTCHINSON: Objection, irrelevant.</p> <p>24</p>

7 (Pages 22 to 25)



Vladimir Iakovlev, M.D.

Page 26	Page 28
<p>1 BY MR. ANDERSON:  2 Q. We have your objection. Answer  3 please.  4 A. No.  5 Q. Did anyone question your experience?  6 A. No.  7 Q. Did anyone question your  8 credibility?  9 A. No.  10 Q. Did anyone question your  11 methodology?  12 A. No.  13 Q. Anyone question any of your  14 conclusions?  15 A. No.  16 Q. Anyone question any of your findings  17 from your peer-reviewed literature at this  18 conference, or any international conference at  19 which you've presented your scientific work on  20 mesh?  21 A. No.  22 Q. Shifting gears now, as part of your  23 daily practice at St. Michael's do you routinely  24 receive foreign bodies or foreign materials like</p>	<p>1 Q. Have you received surgically-removed  2 Ethicon meshes to perform pathological analysis as  3 your role as an anatomic pathologist at St.  4 Michael's Hospital? Let me see if I can ask a  5 better question.  6 In your role as an anatomic pathologist  7 at St. Michael's --  8 A. Yes.  9 Q. -- have you received, from surgeons,  10 Ethicon surgical meshes that have been explanted  11 from patients?  12 A. Yes, I did.  13 Q. And have you received those in order  14 to conduct pathological analysis and  15 clinico-pathological analysis?  16 A. Yes, I did.  17 Q. Approximately how many mesh  18 specimens have you examined in your career as a  19 pathologist?  20 A. Over 300 by now.  21 Q. How many of these would be vaginal  22 meshes versus hernia meshes made out of  23 polypropylene?  24 A. Approximately 100 would be hernia</p>
Page 27	Page 29
<p>1 medical devices that have been removed from  2 patients for which you have been asked to render  3 medical diagnoses and opinion?  4 A. Yes, we receive them regularly.  5 Those devices would be cardiac valves, tissue  6 expanders, breast implants, hip joints, knee  7 joints and meshes.  8 Q. And do those meshes include  9 transvaginal meshes like the TVT-O sling?  10 A. Yes, they do.  11 Q. What are the primary reasons that  12 medical devices, like those you've just listed for  13 the jury, are removed and sent to you in  14 pathology?  15 A. Well, the first reason is we need to  16 document the receipt of the device and then we  17 need to describe it grossly. Then during  18 examination we need to rule out natural disease  19 like cancer which could cause these symptoms. And  20 then we can see what the changes were in the  21 tissue, if the changes were related just to the  22 device or to something else. And also we can  23 describe if the device was failing on its own due  24 to design defect or some other factors.</p>	<p>1 meshes and over 200 would be transvaginal meshes.  2 Q. Those would include meshes made by  3 Ethicon?  4 A. Yes.  5 Q. And those would include  6 polypropylene meshes?  7 A. Most of them are polypropylene  8 meshes.  9 Q. At this time we tender Dr. Vladimir  10 Iakovlev as an expert in the following areas,  11 pathology, anatomic pathology, the pathology of  12 surgical meshes like the TVT-O, microscopic  13 analysis of the changes in the tissue when mesh is  14 implanted in the body, correlation of microscopic  15 pathological findings to mesh patients' medical  16 problems that led to surgical removal of the mesh,  17 and microscopic analysis of the degradation of  18 polypropylene mesh in the human body, including  19 degradation of the TVT-O device.  20 MR. HUTCHINSON: Counsel, we're  21 reserving our objections.  22 BY MR. ANDERSON:  23 Q. Based on your clinical experience as  24 a practicing pathologist, as well as your research</p>

8 (Pages 26 to 29)

Vladimir Iakovlev, M.D.

Page 30	Page 32
<p>1 in analyzing over 300 polypropylene mesh explants,  2 do you have an opinion, to a reasonable degree of  3 medical certainty, as to whether there are  4 anatomic differences between the abdominal wall  5 and the vaginal?  6 A. Yes, there are.  7 Q. What is that opinion, Doctor?  8 A. The anterior abdominal wall is  9 composed of layers of tissue for skin, and some  10 fat, and then muscle, and then fascia, and then  11 all nerves and vessels are run parallel. When the  12 hernia is repaired the mesh is laid flat against  13 all the structures and then the abdominal wall  14 expands slightly and then goes up and down with  15 breathing, but there is not much more action  16 beyond that. So the role of the mesh is just to  17 hold the pressure.  18 Now, if we go to the female pelvis or  19 any pelvis there are no planes. The structures  20 are rounded and they are confined in a conical  21 shape in a confined space so there are no planes  22 in between the organs. The organs gradually  23 transition into each other and there are no planes  24 because the bladder is rounded, and then the</p>	<p>1 area versus the nerve density for a woman's  2 abdominal area something you have published in the  3 peer-reviewed scientific literature?  4 A. Yes. I compared it -- on average if  5 we compare the entire abdominal wall and all areas  6 in the vagina, specifically around slings, the  7 difference is 11 times, over 11 times. The area  8 around slings in the vagina has 11 times more  9 innervation and then the anterior abdominal wall.  10 Q. And what does "innervation" mean?  11 A. Innervation means there are nerves  12 which are supplying the skin to feel it, to feel  13 the surface. Because the genital area needs to be  14 very sensitive, and we know why. And it's --  15 sensation is supplied by the nerves. You have  16 more nerves you have more sensation.  17 Q. Doctor, did we ask you to review  18 materials in this case and to give your expert  19 conclusions with regard to Ms. Jennifer Ramirez?  20 A. Yes.  21 Q. And, Dr. Iakovlev, you understand  22 you'll be expressing some expert conclusions and  23 opinions here today, correct?  24 A. Yes, I do.</p>
Page 31	Page 33
<p>1 vagina is rounded as well and then the rectum also  2 is rounded.  3 And then the innervation comes from the  4 sides and then sprays like this to innervate the  5 bladder, the vagina and the rectum and then the  6 skin around the vagina from outside. So when the  7 mesh is placed it's crossing all this place -- all  8 this path of innervation inside the tissue.  9 Also when the mesh is placed it's not  10 placed parallel to one plane because there are no  11 planes. So it's placed in the tissues somewhere  12 between gradual transition. Also all the meshes  13 in the vagina are placed on the sensitive vaginal  14 mucosa. Mucosa is like skin just inside and it's  15 very close do the surface. Hernia meshes are not  16 put just under the skin. Hernia meshes are put  17 very deep down.  18 Also in the pelvic area there are lots  19 of action. The bladder needs to expand and  20 contract; the vagina needs to change shape during  21 intercourse; the rectum needs to function as well.  22 So it's not like in anterior abdominal where there  23 is not much action.  24 Q. Is the nerve density of the pelvic</p>	<p>1 Q. And can we agree that every opinion  2 you express here today will be to a reasonable  3 degree of medical certainty whether or not I ask  4 that before each question, is that agreed?  5 A. We agree.  6 Q. Doctor, are you here today to offer  7 any expert conclusions other than as an expert  8 pathologist?  9 A. No. I'm a pathologist. I offer any  10 opinions as a pathologist, as a doctor and as a  11 pathologist.  12 Q. And did you use the same approach in  13 this case, in Ms. Ramirez's case, that you do on a  14 day-to-day routine basis as an anatomic  15 pathologist at St. Michael's when you receive  16 explanted medical devices from surgeons there?  17 A. Yes, exactly the same approach.  18 Q. What did you receive in this case in  19 order to arrive at your expert conclusions for the  20 jury here today?  21 A. I received medical records and I  22 received the specimen in formalin.  23 Q. What do you mean by the specimen in  24 formalin? Please be specific for the jury.</p>

9 (Pages 30 to 33)

Vladimir Iakovlev, M.D.

Page 34	Page 36
<p>1 A. Specimen in formalin was the part of</p> <p>2 the sling or two piece of the sling which were</p> <p>3 excised in March 2015.</p> <p>4 Q. From Ms. Ramirez?</p> <p>5 A. From Ms. Ramirez. They were</p> <p>6 preserved in March 2015 in formalin.</p> <p>7 Q. Okay. So for the record just</p> <p>8 briefly summarize your understanding of</p> <p>9 Ms. Ramirez's clinical course for the jury as it</p> <p>10 relates to this case and as it relates to the work</p> <p>11 that you've done in this case.</p> <p>12 A. Ms. Ramirez had hysterectomy and</p> <p>13 implantation of Ethicon TVT-O sling,</p> <p>14 transobturator sling, in September 2010 for mild</p> <p>15 stress urinary incontinence. Later on, sometime</p> <p>16 around November, she started experiencing pain on</p> <p>17 the left side. During examination the left side</p> <p>18 of the string was found to be --</p> <p>19 Q. The left side of the sling did you</p> <p>20 say?</p> <p>21 A. The left side of Ms. Ramirez or left</p> <p>22 side of the sling was found to be bow stringing or</p> <p>23 tight. It was tight and it was producing pain.</p> <p>24 Therefore the decision was to release the tension</p>	<p>1 today in Ms. Ramirez's body.</p> <p>2 Q. You mentioned that the explant</p> <p>3 samples of the TVT-O mesh that was removed from</p> <p>4 Ms. Ramirez in March of 2015 was preserved by the</p> <p>5 surgeon in formalin. Is that what you said?</p> <p>6 A. That's correct.</p> <p>7 Q. Can you please explain to the jury</p> <p>8 what formalin is?</p> <p>9 A. Formalin is preservative. It's been</p> <p>10 used for over a hundred years. It's a standard</p> <p>11 preservative for tissue. We preserve all</p> <p>12 specimens, all biopsies in formalin to do our</p> <p>13 microscopic examination. It preserves tissue and</p> <p>14 it can stay in formalin pretty much forever, it</p> <p>15 will not degrade.</p> <p>16 Q. And did you analyze everything that</p> <p>17 was made available to you?</p> <p>18 A. Yes.</p> <p>19 Q. Did you use the same procedures in</p> <p>20 that analysis that you would with any similar</p> <p>21 specimen in your daily practice?</p> <p>22 A. Yes. They were analyzed exactly the</p> <p>23 same way. They were loaded into the same machine</p> <p>24 and the machine was in the same protocol as any</p>
Page 35	Page 37
<p>1 and to excise a part of it. And in December 2010</p> <p>2 one centimeter of the sling was excised.</p> <p>3 Then Ms. Ramirez continued to have some</p> <p>4 symptoms and it continued on up to 2014 and 2015.</p> <p>5 She continued to have pain on the left side and</p> <p>6 also she had some urinary obstructive symptoms.</p> <p>7 She was examined, the treating doctor</p> <p>8 examined her, did investigations and the final</p> <p>9 decision was to excise the residual part of the</p> <p>10 sling. So in March 2015 the residual part which</p> <p>11 could be excised was excised. Two pieces of two</p> <p>12 centimeters were excised.</p> <p>13 Q. Is that the part that you received</p> <p>14 in order to analyze?</p> <p>15 A. Yes, I did.</p> <p>16 Q. Okay. Go ahead.</p> <p>17 A. I received two parts.</p> <p>18 Q. Okay.</p> <p>19 A. But those side parts or lateral,</p> <p>20 lateral means further sideways. Lateral parts are</p> <p>21 still remaining in the body. They could not be</p> <p>22 removed. They are too deep inside the muscle in</p> <p>23 the obturator space. Both the left and the right</p> <p>24 sides are deep inside and they are still here</p>	<p>1 other diagnostic specimen.</p> <p>2 Q. Do you know how the specimen was</p> <p>3 handled before it came to you?</p> <p>4 A. It was preserved in formalin. I did</p> <p>5 not see any indication that it was outside of</p> <p>6 regular range of handling as I see every day.</p> <p>7 Q. And how do you determine that as a</p> <p>8 pathologist to see if there was anything that was</p> <p>9 done irregular in terms of the handling before it</p> <p>10 came to you?</p> <p>11 A. Well I can see what's the end</p> <p>12 result. If the end result is unacceptable</p> <p>13 something was done not correctly.</p> <p>14 Q. Okay. And what did you do when you</p> <p>15 received that tissue?</p> <p>16 A. When I received the tissue we</p> <p>17 divided it with the defense consultant. Each</p> <p>18 piece, and I mentioned I received two pieces of</p> <p>19 the excised sling. Each piece was divided in</p> <p>20 half. One half was retained by the defense</p> <p>21 consultant and the other halves were analyzed at</p> <p>22 St. Michael's laboratory. I prepared microscopic</p> <p>23 slides out of these two pieces.</p> <p>24 Q. Explain to the jury how you prepared</p>

10 (Pages 34 to 37)

Vladimir Iakovlev, M.D.

Page 38	Page 40
<p>1 the microscopic slides from Ms. Ramirez's surgery 2 in March of 2015 that you're going to show to them 3 today.</p> <p>4 A. When we receive a specimen --</p> <p>5 Q. Specifically talk about what you did 6 with Ms. Ramirez's sample. I know you said you do 7 it the same way every day but let's talk about her 8 sample if we could, Doctor.</p> <p>9 A. When I received her specimen I 10 examined it grossly. I felt it with my hands, and 11 we will describe it later with pictures how it 12 looked grossly.</p> <p>13 Q. Okay.</p> <p>14 A. And then to look inside we need to 15 cut very thin slices. It's like I explain earlier 16 it's like slicing bread. And when we slice it 17 really thinly then we can put the slices of the 18 excised tissue on the glass slide like this.</p> <p>19 Q. Is that one of the slides that has 20 some of Ms. Ramirez's tissue on it?</p> <p>21 A. Yes. This is a slide and it's 22 labelled correctly with Ms. Ramirez's name. It 23 contains slices of the tissue I received and which 24 were removed in March 2015 from Ms. Ramirez's</p>	<p>1 Q. And did you use any other type of 2 staining other than H&amp;E on any of Ms. Ramirez's 3 slides?</p> <p>4 A. I also used newer techniques which 5 were developed relatively recently, like 50 years 6 ago, these are called "immunostains". These are 7 specific stains against specific proteins. And 8 when the protein is present the color is brown, 9 when the protein is not present or where in the 10 areas where there is no protein it's blue.</p> <p>11 Q. What types of features in the tissue 12 can the blue versus brown staining help you as a 13 pathologist to identify?</p> <p>14 A. For example, if I want to see nerves 15 better I can use S100 protein and then the nerves 16 will turn brown.</p> <p>17 Q. On the slide?</p> <p>18 A. On the slide and I can see them 19 easily.</p> <p>20 Q. Did you use any other standard 21 pathological methods in your industry to analyze 22 Ms. Ramirez's explanted tissue to arrive at your 23 opinions that you will be offering to the jury 24 today?</p>
Page 39	Page 41
<p>1 body.</p> <p>2 Q. How many of the slides did you stain 3 for her?</p> <p>4 A. Seven.</p> <p>5 Q. And what types of staining did you 6 use for those seven slides?</p> <p>7 A. Because we cut them so thin they 8 become transparent, so in order to see what 9 structured -- what is what in this -- in the 10 tissue we need to stain it. Staining is like 11 dyeing a fabric. We use some dyes or some stains 12 and then we apply it and then some parts become 13 pink, some parts become blue and then I can see 14 them in the microscope.</p> <p>15 There is one basic stain, the first 16 stain we usually do, it's called hematoxylin eosin 17 or in short we call it H&amp;E. "H" means 18 hematoxylin, "E" means eosin. Eosin stains 19 proteins pink, hematoxylin stains nuclei blue. 20 All inflammatory cells stain blue, all scar tissue 21 stains pink.</p> <p>22 Q. How long has H&amp;E staining been 23 around and used by pathologists?</p> <p>24 A. Around a hundred years.</p>	<p>1 A. Yes, I did.</p> <p>2 Q. What was that?</p> <p>3 A. Well first I use regular light on 4 the microscope and then I use polarizing light.</p> <p>5 Q. And we will get into those finding 6 about your polarizing light a little bit later 7 okay?</p> <p>8 A. Okay.</p> <p>9 Q. Did you have the actual piece of 10 mesh or the pieces of mesh that were removed from 11 Ms. Ramirez's body in March of 2015?</p> <p>12 A. Yes, I had them.</p> <p>13 Q. Okay. Did you have the pathology 14 report issued by the hospital's pathologist who 15 received the tissue right after it was removed 16 from her body on March 10, 2015?</p> <p>17 A. Yes, I had.</p> <p>18 Q. And is that something that you 19 reviewed and relied upon in forming your opinions 20 in this case?</p> <p>21 A. Yes.</p> <p>22 Q. I'll hand you what has been marked 23 as plaintiff's Exhibit 3.</p> <p>24 ---PLAINTIFF EXHIBIT NO. 3: Pathology</p>

11 (Pages 38 to 41)

Vladimir Iakovlev, M.D.

Page 42	Page 44
<p>1 report from UT Southwestern Medical</p> <p>2 Center re. Jennifer Ramirez, printed</p> <p>3 4/1/2015.</p> <p>4 BY MR. ANDERSON:</p> <p>5 Q. Can you first identify that for the</p> <p>6 record? And can you publish that please?</p> <p>7 A. This is a pathology from UT</p> <p>8 Southwestern Medical Center. It has name of</p> <p>9 Ramirez Jennifer with date of birth March 10,</p> <p>10 1982.</p> <p>11 Q. What's the date of this record?</p> <p>12 A. The specimen collection date is</p> <p>13 March 10, 2015.</p> <p>14 Q. What did the pathologist describe in</p> <p>15 his pathology report of March 10, 2015?</p> <p>16 A. So the final pathology diagnosis</p> <p>17 was, "Vaginal mesh removal, synthetic mesh</p> <p>18 material with embedded fibrous tissue with chronic</p> <p>19 inflammation. No evidence of malignancy."</p> <p>20 Q. Okay. Let's get that whole final</p> <p>21 diagnosis up there. Thank you.</p> <p>22 A. There was also clinical --</p> <p>23 Q. Can you expand down to bottom</p> <p>24 please?</p>	<p>1 Q. What is the primary reason that</p> <p>2 tissue is sent to pathology departments around</p> <p>3 North America every day?</p> <p>4 A. Well the most important reason any</p> <p>5 pathology is sent to rule out malignancy because</p> <p>6 we know malignancies kill.</p> <p>7 Q. And malignancy meaning?</p> <p>8 A. Cancers.</p> <p>9 Q. Is this what this initial</p> <p>10 pathologist did?</p> <p>11 A. Yes.</p> <p>12 Q. And was that the end of his</p> <p>13 analysis.</p> <p>14 A. Well, it was not exactly the end.</p> <p>15 Q. Okay.</p> <p>16 A. He described more what is abnormal</p> <p>17 in the tissue. First he sees no cancer and he</p> <p>18 reports it, and then he describes what is</p> <p>19 abnormal. And the abnormality in the tissue is</p> <p>20 synthetic mesh with fibrous tissue and chronic</p> <p>21 inflammation. These are all pathological. We</p> <p>22 normally don't have foreign bodies when we are</p> <p>23 born, we don't have scarring when we are born and</p> <p>24 we don't have inflammation.</p>
Page 43	Page 45
<p>1 A. There was also clinical information</p> <p>2 provided with the specimen.</p> <p>3 Q. What clinical information was</p> <p>4 provided?</p> <p>5 A. "Urinary dysfunction", and then,</p> <p>6 "Questioned vaginal removal of suburethral tape."</p> <p>7 Q. Do the findings that you are going</p> <p>8 to show us here today differ from those made by</p> <p>9 the pathologist at the hospital where Ms. Ramirez</p> <p>10 had her mesh removed?</p> <p>11 A. No.</p> <p>12 Q. Please explain.</p> <p>13 A. So we had exactly the same findings</p> <p>14 that the material I received and the material</p> <p>15 which was examined at UofT Southwestern Medical</p> <p>16 Center contained the only pathological abnormality</p> <p>17 of a mesh and tissue reaction to the mesh. There</p> <p>18 was no natural disease like malignancy. And</p> <p>19 correctly the pathologist answered the question of</p> <p>20 the treating doctor that it is indeed suburethral</p> <p>21 tape. See there is a question mark and he</p> <p>22 answered, yes, it is suburethral tape or TVT-O</p> <p>23 tape remove and there is no malignancy in the</p> <p>24 specimen.</p>	<p>1 Q. As part of your work in this case,</p> <p>2 and after your review of the various stained</p> <p>3 slides that you prepared at St. Michael's, did you</p> <p>4 have additional findings to those of the hospital</p> <p>5 pathologist?</p> <p>6 A. Yes, I did.</p> <p>7 Q. Can you explain that?</p> <p>8 A. Well, because I was asked more</p> <p>9 questions. I was asked to show or to report to</p> <p>10 the Court and to the jury if pathological findings</p> <p>11 correlate with the clinical presentation or with</p> <p>12 the complications. So my first answer was the</p> <p>13 same as for the pathologist, but since I was asked</p> <p>14 to review this specimen in view of the litigation</p> <p>15 I went one step further. I correlated those</p> <p>16 pathological findings, which are the same, with</p> <p>17 the symptoms.</p> <p>18 Q. Did you endeavor to determine</p> <p>19 whether or not from your analysis of the slides</p> <p>20 and your review of the records as to what your own</p> <p>21 pathological differential diagnosis was?</p> <p>22 A. Yes, I did.</p> <p>23 Q. And did you see if you could</p> <p>24 determine whether those could be correlated to the</p>

12 (Pages 42 to 45)



Vladimir Iakovlev, M.D.

Page 46	Page 48
<p>1 clinico-differential diagnosis by Ms. Ramirez's</p> <p>2 treating doctors?</p> <p>3 A. Yes, I did.</p> <p>4 Q. And were you able to do that?</p> <p>5 A. Yes, I was able to do that.</p> <p>6 Q. And are those the expert conclusions</p> <p>7 you're going to offer to the jury here today?</p> <p>8 A. Yes.</p> <p>9 Q. After you did the staining of</p> <p>10 Ms. Ramirez's slides what did you do next?</p> <p>11 A. Then I examined the slides in the</p> <p>12 microscope. First I needed to see what's abnormal</p> <p>13 in the tissue and then further examine in details</p> <p>14 the abnormalities in the tissue.</p> <p>15 Q. Did you also review her medical</p> <p>16 records?</p> <p>17 A. Yes, I did.</p> <p>18 Q. Okay.</p> <p>19 A. I needed to know the background,</p> <p>20 what were the initial reasons why the sling was</p> <p>21 implanted, and then what type of sling was</p> <p>22 implanted, and when it was implanted and the</p> <p>23 reason why it was implanted. First of all to</p> <p>24 understand what device I'm looking at, second to</p>	<p>1 take all of that into consideration before forming</p> <p>2 your expert conclusion?</p> <p>3 A. Yeah, I was basing -- I was reliant</p> <p>4 on this clinical information, on the work-up of</p> <p>5 treating doctors which was done for Ms. Ramirez.</p> <p>6 Q. And are you here today to offer any</p> <p>7 opinions as to whether or not her treating doctors</p> <p>8 complied with the standard of care?</p> <p>9 A. No.</p> <p>10 Q. Did you take photographs of the</p> <p>11 slides that were under the microscope?</p> <p>12 A. Yes, I did.</p> <p>13 Q. And what did you take those</p> <p>14 photographs with?</p> <p>15 A. With a camera, something similar</p> <p>16 like this.</p> <p>17 Q. Like the one that's sitting on top</p> <p>18 of the microscope next to you here today?</p> <p>19 A. Yes, something like this.</p> <p>20 Q. What's the purpose of taking</p> <p>21 photographs of the slides while they're on the</p> <p>22 microscope?</p> <p>23 A. To document my findings and to show</p> <p>24 them to the jury and to the Court.</p>
Page 47	Page 49
<p>1 correlate the pathological changes with the</p> <p>2 reasons for explantation. Because when the</p> <p>3 physicians were going through the differential</p> <p>4 diagnosis they ruled out several entities but then</p> <p>5 the decision was to excise due to specific</p> <p>6 reasons.</p> <p>7 MR. HUTCHINSON: Move to strike as</p> <p>8 nonresponsive.</p> <p>9 BY MR. ANDERSON:</p> <p>10 Q. I asked you whether or not you</p> <p>11 reviewed medical records, correct?</p> <p>12 A. That's correct.</p> <p>13 Q. What was your purpose for reviewing</p> <p>14 those medical records?</p> <p>15 A. My purpose was to see what type of</p> <p>16 device was; if there was foreign body indeed</p> <p>17 implanted; what symptoms were developing and what</p> <p>18 symptoms triggered excision of the mesh.</p> <p>19 Q. Was it significant to your analysis</p> <p>20 and ultimately your opinions as to what mesh was</p> <p>21 implanted, why it was implanted, and when it was</p> <p>22 explanted and why it was explanted?</p> <p>23 A. Yes, it was significant.</p> <p>24 Q. And did you review all of that and</p>	<p>1 Q. Did you bring photomicrographs of</p> <p>2 Ms. Ramirez's slides that you prepared here with</p> <p>3 you today?</p> <p>4 A. Yes, I did.</p> <p>5 Q. Are they significant to your</p> <p>6 opinions in this case?</p> <p>7 A. Yes, they are.</p> <p>8 Q. Did you also bring the slides</p> <p>9 themselves? I see those are in front of you here</p> <p>10 today?</p> <p>11 A. Yes. These are the slides.</p> <p>12 Q. Would it be helpful to show them to</p> <p>13 the jury?</p> <p>14 A. So I'm showing this to the jury.</p> <p>15 Q. And are those the different stains</p> <p>16 of these --</p> <p>17 A. These are different stains and these</p> <p>18 three are H&amp;E stains, the one I just explained</p> <p>19 hematoxylin and eosin. And these three are</p> <p>20 immunostains, those blue and brown stains as I</p> <p>21 explained. And they are done by slicing the</p> <p>22 tissue like bread.</p> <p>23 Q. Okay.</p> <p>24 A. And then the slices are put on the</p>

13 (Pages 46 to 49)

Vladimir Iakovlev, M.D.

Page 50	Page 52
<p>1 glass slide, and then to see what is what in the 2 tissue we stain them. 3 Q. Okay. 4 A. And here are different stains. 5 Q. Okay. We talked about 6 photomicrographs. You can put that down. We 7 talked about photomicrographs. Did you bring some 8 here today to show the jury? 9 A. Yes. 10 Q. Are these the same ones that would 11 have been provided previously to Ethicon's 12 lawyers? 13 A. Yes, they were. 14 Q. I'm showing you what we will mark as 15 a document set which will be 4(A) through 4(M) 16 ---PLAINTIFF EXHIBIT NO. 4(A) to 4(M): 17 Series of photographs taken by Dr. 18 Iakovlev during the examination of 19 Jennifer Ramirez's specimen. 20 BY MR. ANDERSON: 21 Q. Please identify this document set 22 4(A) through 4(M), Doctor. 23 A. These are photographs I took during 24 the examination of the specimen of Ms. Ramirez</p>	<p>1 is curled, which will show better on the next 2 photograph. 3 Q. Let's go to plaintiff's Exhibit 4 4(C). Can you identify this for the record? 5 A. So this is a combined image of 6 previous gross photograph and two microscopic 7 images. 8 Q. Explain what we're seeing on the 9 left please, Dr. Iakovlev? 10 A. On the left there is a diagram 11 showing how we take slices. As I explained we 12 slice the tissue to make microscopic slides. It's 13 like taking slice of bread. So this would be a 14 slice, like this. And from this piece the slice 15 was taken parallel to the piece or flat to the 16 surface. It's like if we take a loaf of bread and 17 for the top piece the loaf of bread would be cut 18 perpendicular and for the bottom piece the loaf of 19 bread would be cut longitudinal. 20 Q. And are those two of the slides that 21 you showed the jury on this slide board here just 22 a few minutes ago? 23 A. Yes, they are exactly the same two 24 slides.</p>
Page 51	Page 53
<p>1 which was removed from her body in March 2015. 2 Some of these are gross photographs and some of 3 them are microscopic photographs. 4 Q. You mentioned gross photographs. 5 Can we please put Exhibit 4(A) up? 6 A. So the gross photograph is something 7 which we see with naked eye, without the 8 microscope. And these are the two pieces that I 9 received. And this is the identifier for the 10 surgical case for St. Michael's Hospital. And we 11 can see here that these two pieces correspond to 12 what was correctly described as two pieces, 13 approximately 2 centimeter each. One appears to 14 be wider here, one is narrow here. And I will 15 show on the next photograph why one is wider and 16 one is a little bit narrower. 17 Q. Okay. Let's publish plaintiff's 18 4(B) please. What's the jury seeing in this 19 picture? 20 A. These are the same two pieces of 21 Ms. Ramirez's specimen which was removed in March 22 2015. Now it's a close-up and it's slightly 23 different angle. And now I can show that one 24 piece is -- this piece is flat and the other one</p>	<p>1 Q. Okay. In your opinion, Doctor, what 2 degree of scarring -- well, go ahead. 3 A. These are H&amp;E stained slides. The 4 scar tissue, as I explained, stains pink. And you 5 can see pink color in between those clear spaces 6 and pink color here in between those clear spaces. 7 Now, why they are clear? Because 8 polypropylene is clear, it's like fishing line. 9 If there is no color in it it's clear. But some 10 fibers of the mesh are colored blue, and you can 11 see some of them blue here. Now, all these spaces 12 in between fibers are filled with scar tissue. To 13 help the jury to understand where the mesh fibers 14 are and where the tissue is I colored mesh fibers 15 with yellow color on the next image. 16 Q. Okay. Can we see 4(D)? Please 17 identify this for the jury. 18 A. These are exactly the same images as 19 you saw before. I just put yellow color in the 20 spaces where the mesh fibers are or were while in 21 the body of Ms. Ramirez. And -- 22 Q. In your opinion, Dr. Iakovlev, what 23 degree of scarring is shown in Ms. Ramirez's 24 specimen?</p>

14 (Pages 50 to 53)



Vladimir Iakovlev, M.D.

<p style="text-align: right;">Page 54</p> <p>1 A. There is one hundred percent</p> <p>2 scarring. All the tissue we see here, all pink</p> <p>3 tissue is scar tissue.</p> <p>4 Q. Is there any healthy tissue in and</p> <p>5 around the fibers of the explant as demonstrated</p> <p>6 in Exhibit 4(D)?</p> <p>7 A. No, there is none. What happens</p> <p>8 when we damage the tissue or there is an empty</p> <p>9 space in the body it becomes filled with scar</p> <p>10 tissue. Our body heals through producing a scar</p> <p>11 tissue. And in this case this space in between</p> <p>12 mesh fibers did not exist before the mesh was</p> <p>13 placed. It became filled with scar tissue during</p> <p>14 healing.</p> <p>15 Q. Are you familiar with the term</p> <p>16 "bridging fibrosis"?</p> <p>17 A. Yes, I am.</p> <p>18 Q. Can you please explain?</p> <p>19 A. So as you can see scar tissue fills</p> <p>20 the spaces between mesh fibers or bridges from one</p> <p>21 fiber to another, from one fiber to another. So</p> <p>22 this is bridging fibrosis. Fibrosis and scarring</p> <p>23 are the same.</p> <p>24 Q. Okay. Are you familiar with the</p>	<p style="text-align: right;">Page 56</p> <p>1 when it matures, when it heals, it contracts. The</p> <p>2 body tries to minimize, to shrink the area of</p> <p>3 damage. But when it contracts it's not as</p> <p>4 flexible and it also pulls the tissue together so</p> <p>5 people cannot move some arms if it's a large area.</p> <p>6 The same happens with the scar tissue which is</p> <p>7 inside the mesh. It pulls all the mesh fibers</p> <p>8 together, it shrinks. And in terms of TVT or</p> <p>9 TVT-O sling it tightens the sling because it</p> <p>10 contracts within, it pulls everything together.</p> <p>11 Q. Does it -- does contraction cause</p> <p>12 the mesh implant to be stiffer or more flexible?</p> <p>13 A. It becomes stiffer. Because you can</p> <p>14 see scar tissue here is very dense. It's like a</p> <p>15 tendon. It's as dense as tendon.</p> <p>16 Q. Based on those images, and your</p> <p>17 overall analysis of Ms. Ramirez's explant, do you</p> <p>18 have an opinion to a reasonable degree of medical</p> <p>19 certainty as to whether the TVT-O sling contracted</p> <p>20 while in Ms. Ramirez's body?</p> <p>21 A. Yes, I do.</p> <p>22 Q. And what is that opinion?</p> <p>23 A. My opinion is that TVT-O contracted</p> <p>24 while it was in Ms. Ramirez's body.</p>
<p style="text-align: right;">Page 55</p> <p>1 term "scar plating" and "scar encapsulation"?</p> <p>2 A. Yes.</p> <p>3 Q. Can you please explain those and</p> <p>4 whether or not we see those in Exhibit 4(D)?</p> <p>5 A. Scar encapsulation happens with all</p> <p>6 foreign bodies. All foreign bodies become</p> <p>7 isolated from the body. The body tries to isolate</p> <p>8 them and encase them in scar tissue. So this</p> <p>9 would be scar encapsulation. Together with the</p> <p>10 scar inside, the scar from outside, this would be</p> <p>11 capsule and scar inside is bridging fibrosis, and</p> <p>12 they all together they form one solid structure.</p> <p>13 It's like concrete filling the spaces in between</p> <p>14 the rebar. Rebar would be the mesh fibers and the</p> <p>15 concrete would be scar tissue. It solidifies the</p> <p>16 area and holds all mesh fibers within the scar</p> <p>17 tissue.</p> <p>18 Q. Are you familiar with the term "mesh</p> <p>19 contraction" sometimes known as "mesh shrinkage"?</p> <p>20 A. Yes, I am.</p> <p>21 Q. What is that and how does it occur?</p> <p>22 A. We know that all scar tissue in the</p> <p>23 body contracts. You've probably seen some burn</p> <p>24 victim when there is a large area and scar tissue</p>	<p style="text-align: right;">Page 57</p> <p>1 Q. Is there anything else descriptive</p> <p>2 in these images that you'd like to explain to the</p> <p>3 jury?</p> <p>4 A. That's interesting because, as I</p> <p>5 explained, one piece is flat the other -- one</p> <p>6 piece is curled. And the next image will show the</p> <p>7 plain of curling in the top image.</p> <p>8 Q. Can we see 4(E) please? Please</p> <p>9 identify this for the jury and explain how it</p> <p>10 relates to your opinions in this case?</p> <p>11 A. These are the same images we just --</p> <p>12 we saw before but the difference is I put this</p> <p>13 thick yellow band to show how the sling curled.</p> <p>14 So the sling, or TVT-O tape, curled in this piece,</p> <p>15 or what sometimes treating doctors call "roped" or</p> <p>16 there is a roping, or in this for Ms. Ramirez it</p> <p>17 was called "bow stringing". It was like a tight</p> <p>18 bow string.</p> <p>19 And it happened because it curled up and</p> <p>20 the space within the curl or within the roll was</p> <p>21 filled with scar tissue. It's like concrete. It</p> <p>22 filled the space within that's why it shows that</p> <p>23 that curling occurred inside the body, which</p> <p>24 correlates with the clinical description of bow</p>

15 (Pages 54 to 57)

Vladimir Iakovlev, M.D.

<p style="text-align: right;">Page 58</p> <p>1 stringing. Because it was curled up like a rope,  2 it was filled with dense scar tissue and it  3 occurred in the body.  4 Q. Doctor, hypothetically if there is  5 testimony in this case that these slides that the  6 jury has been looking at show normal tissue around  7 and in between these mesh fibers, do you have an  8 opinion to a reasonable degree of medical  9 certainty about that?  10 A. I do.  11 Q. And what is that opinion?  12 A. My opinion is there is one hundred  13 percent scar tissue. There is no normal tissue  14 anywhere in this specimen. All of the tissue in  15 between mesh fibers is scar tissue, dense scar  16 tissue as dense as a tendon.  17 Q. Thank you, Doctor. If we could show  18 Exhibit 4(F) and 4(G). Can you please identify  19 those for the record?  20 A. These are microscopic images of the  21 specimen which was taken out of Ms. Ramirez's body  22 in March 2015. This is a higher power  23 magnification. These are two images. One image  24 is original image on the top, and the second image</p>	<p style="text-align: right;">Page 60</p> <p>1 the macrophages.  2 In terms of foreign bodies the same  3 thing happens with the foreign bodies. The body  4 sends these fighter cells to degrade or destroy  5 the foreign body and they will be surrounding this  6 foreign body as long as the foreign body stays in  7 the body.  8 So what they do when they come they  9 start producing all this reactive chemicals which  10 can destroy, and which are designed to destroy and  11 degrade the foreign body and bacteria, and they  12 will stay there and they will produce these  13 reactive chemicals.  14 Q. Is the inflammation that we see in  15 Exhibits 4(F) and 4G transient or temporary  16 inflammation?  17 A. Absolutely not.  18 Q. Please explain.  19 A. This inflammation, this foreign body  20 type inflammation will stay as long as the foreign  21 body stays in the body.  22 Q. You're familiar with the term  23 "chronic" on "permanent inflammation"?  24 A. Yes, I am.</p>
<p style="text-align: right;">Page 59</p> <p>1 is the same image but I just filled the spaces  2 where the mesh fibers are with yellow color just  3 to help the jury to orient where the mesh fibers  4 are.  5 Now, we can see pink color, which you  6 saw before. This is scar tissue, the same scar  7 tissue, but there is something in between like a  8 halo around the mesh fibers, in between mesh  9 fibers and the scar tissue. And this halo is  10 purple and then it has these dark blue dots.  11 These dark blue dots are nuclei of macrophages.  12 Q. Are nuclei of macrophages. Okay,  13 we're not all pathologists so can you just explain  14 to the jury what nuclei of macrophages are and why  15 that's important, in your view, regarding these  16 images?  17 A. Nuclei are center of the cell, it's  18 like a brain of the cell. It controls everything.  19 Macrophages are the fighter cells. The body sends  20 macrophages to fight with something which is  21 damaging the body, either bacteria or foreign  22 bodies. When the bacteria comes to macrophages  23 come and then they try to either destroy, dissolve  24 them or swallow them up and then destroy within</p>	<p style="text-align: right;">Page 61</p> <p>1 Q. What does that mean?  2 A. "Chronic" means long-term.  3 "Permanent" means forever.  4 Q. Is this chronic or permanent  5 inflammation from Ms. Ramirez's slides?  6 A. This is chronic and permanent as  7 long as foreign body stays in the body. This part  8 was removed but the lateral parts, the side parts,  9 deeper parts, are still in the body of  10 Ms. Ramirez.  11 Q. Do you have an opinion to a  12 reasonable degree of medical certainty as to  13 whether or not the pieces of the TVT-O sling that  14 are still in Ms. Ramirez continue to have chronic,  15 permanent inflammation in and around the mesh  16 fibers?  17 A. Yes, they will.  18 Q. Do you have an opinion, to a  19 reasonable degree of medical certainty, as to  20 whether or not Ms. Ramirez's TVT-O mesh caused the  21 chronic foreign body type inflammation, fibrotic  22 bridging, scar plating, scar encapsulation,  23 curling, roping and mesh contraction that you have  24 identified in these images?</p>

16 (Pages 58 to 61)

Vladimir Iakovlev, M.D.

Page 62	Page 64
<p>1 A. Yes, I am.</p> <p>2 MR. HUTCHINSON: Objection, foundation.</p> <p>3 THE DEPONENT: Yes. I do have this --</p> <p>4 BY MR. ANDERSON:</p> <p>5 Q. What is that opinion?</p> <p>6 A. My opinion is that mesh which was</p> <p>7 implanted into Ms. Ramirez's body caused bridging</p> <p>8 fibrosis, scar encapsulation, scar plating, nerve</p> <p>9 entrapment, chronic foreign body reaction, scar</p> <p>10 contraction and sling tightening while it was in</p> <p>11 Ms. Ramirez's body.</p> <p>12 Q. Doctor, you just mentioned bridging</p> <p>13 fibrosis, scar encapsulation, scar plating, nerve</p> <p>14 contraction and sling tightening while the mesh</p> <p>15 was in Ms. Ramirez's body. Do you remember that?</p> <p>16 A. I do.</p> <p>17 Q. In your review of over 300 explanted</p> <p>18 meshes, in the publications that you have put in</p> <p>19 the peer-reviewed literature, at the conferences</p> <p>20 at which you have spoken, international</p> <p>21 conferences around the world, have you been able</p> <p>22 to determine that there were similar findings in</p> <p>23 those or some of those mesh explants?</p> <p>24 MR. HUTCHINSON: Objection, foundation.</p>	<p>1 hematoxylin eosin or H&amp;E.</p> <p>2 Q. Now let's go to images 4(J) and --</p> <p>3 oh wait. Go ahead.</p> <p>4 A. I wanted to show one area here.</p> <p>5 Q. Okay. So can you please describe in</p> <p>6 the upper and lower image where these nerve</p> <p>7 branches are and what is surrounding the nerve</p> <p>8 branches?</p> <p>9 A. So these are the nerve branches and</p> <p>10 this is part of the mesh, or mesh fibers. And the</p> <p>11 nerve branches are entrapped in scar tissue. So</p> <p>12 this would be the same magnification but in a</p> <p>13 labelled image. So these are nerve branches but</p> <p>14 it's somewhat difficult to see them in H&amp;E section</p> <p>15 so I use a different stain to show them better.</p> <p>16 Q. You mentioned before an S100</p> <p>17 staining to the jury?</p> <p>18 A. That's correct.</p> <p>19 Q. Did you do S100 staining of these</p> <p>20 same slides?</p> <p>21 A. Yes, I did.</p> <p>22 Q. And did you bring those here with</p> <p>23 you today to show the jury?</p> <p>24 A. Yes.</p>
Page 63	Page 65
<p>1 THE DEPONENT: Yes, I was able to.</p> <p>2 These findings occur in almost all mesh specimens</p> <p>3 to a degree, to different degrees, but all this is</p> <p>4 happening in all mesh specimens.</p> <p>5 BY MR. ANDERSON:</p> <p>6 Q. And that's been reported in your</p> <p>7 peer-reviewed literature?</p> <p>8 MR. HUTCHINSON: Objection, leading.</p> <p>9 BY MR. ANDERSON:</p> <p>10 Q. Has that been reported in your</p> <p>11 peer-reviewed literature?</p> <p>12 A. It has been reported in</p> <p>13 peer-reviewed literature before I started research</p> <p>14 and then I continued the work and I published the</p> <p>15 same findings.</p> <p>16 Q. Showing you what's been marked as</p> <p>17 plaintiff's Exhibits 4(H) and 4(I). Please</p> <p>18 identify these images. First identify them for</p> <p>19 the jury and then we'll talk about what they show.</p> <p>20 A. These are -- this is one image. One</p> <p>21 is unlabelled the other one is labelled. It's a</p> <p>22 microphotograph of the area of the specimen which</p> <p>23 was removed in March 2015 from Ms. Ramirez's body.</p> <p>24 The same type of staining as you saw before called</p>	<p>1 Q. Can you publish 4(J) and 4(K).</p> <p>2 Doctor, are 4(J) and 4(K) the same tissue sample</p> <p>3 as 4(H) and 4(I) that the jury just saw?</p> <p>4 A. Yeah. It's exactly the same area</p> <p>5 it's just a different stain. These mesh fibers</p> <p>6 are the same you saw before.</p> <p>7 Q. What is the blue area that the jury</p> <p>8 is seeing?</p> <p>9 A. Blue here is a different dye</p> <p>10 staining scar tissue. So scar tissue can be</p> <p>11 stained pink in H&amp;E and in this stain it's blue.</p> <p>12 Now, if we zoom in now we can see that the nerve</p> <p>13 branches or nerves are staining brown. This is</p> <p>14 the mesh fiber, this is scar tissue and these are</p> <p>15 nerves which are sitting in the scar tissue.</p> <p>16 Q. Are those nerves -- strike that.</p> <p>17 Are there different types of nerves in</p> <p>18 the human body? First answer that question. Are</p> <p>19 there different types of nerves in the human body?</p> <p>20 A. There are.</p> <p>21 Q. Are you familiar with the terms</p> <p>22 "sensory nerves" and "motor nerves"? Are you</p> <p>23 familiar with the term?</p> <p>24 A. I'm familiar with the term but it's</p>

17 (Pages 62 to 65)

Vladimir Iakovlev, M.D.

Page 66	Page 68
<p>1 slightly incorrect term, sensory nerves of motor 2 nerves. 3 Q. Can you please explain that? 4 A. Most of the nerves in our body are 5 mixed. What is separate, sensory versus motor, 6 are fibers. So a nerve is like a bundle, like a 7 thick capable containing multiple wires and the 8 wires inside are nerve fibers, but the nerve 9 itself contains multiple nerve fibers. So one 10 fiber can be motor, one fiber can be sensory but 11 they are all together in one nerve. 12 Q. So are these nerves that we see here 13 mixed nerves, like you just described, or are they 14 separated? 15 A. To a reasonable degree of medical 16 certainty these nerves are mixed. Another 17 additional piece of information is where are we in 18 the body specifically for this specimen? 19 Q. Okay. 20 A. This was excised right underneath 21 vaginal mucosa. 22 Q. Why is that significant to your 23 opinion? 24 MR. HUTCHINSON: Move to strike as</p>	<p>1 show. 2 A. This is another image of the nerves, 3 brown staining, however, this one shows that the 4 nerves are within the mesh. They are between the 5 fibers. So these nerves, and I will zoom in, 6 these nerves they grew into the mesh spaces after 7 the mesh was placed. 8 Q. Why is that significant to your 9 opinion? 10 A. Because these nerves are not just 11 trapped in the scar tissue. They are also trapped 12 in the mesh. So when the mesh was placed the 13 nerves grew through the pores of the mesh and 14 became trapped in the mesh. So, first of all they 15 are in scar tissue firmly fixed, immobilized in 16 scar tissue. Second, they are within the pores. 17 So if the sling is moved or contracted they will 18 pull on the nerves. 19 Q. What's the effect of pulling on the 20 nerves in this fashion to the body? 21 A. It will produce pain. It's like 22 pinched pain or pulled nerve. Pinched nerve or 23 pulled nerve. 24 Q. Okay.</p>
Page 67	Page 69
<p>1 nonresponsive. 2 THE DEPONENT: It is significant -- 3 BY MR. ANDERSON: 4 Q. Hold on. So you explain that the -- 5 to a reasonable degree of medical certainty these 6 nerves are mixed nerves, correct? 7 A. That's correct. 8 Q. What area of the body are these 9 nerves coming from and is that significant to your 10 opinions? 11 A. They come from underneath of vaginal 12 mucosa and it is significant to my opinions. 13 Q. Why? 14 A. Because in that area most of the 15 function of the nerves is to supply sensation from 16 vaginal mucosa. There is not much motor function 17 in the area. There are no more large organs. The 18 bladder is all the way back. There are no more 19 muscles here. They are right next to mucosa. 20 There is not much else to do for the nerves other 21 than just provide sensation from the mucosa. 22 Q. Okay. Let's look at the next 23 photograph, 4(L) and 4(M). Please identify these 24 images for the jury and then explain what they</p>	<p>1 A. Also because they are in this tight 2 space and within dense scar tissue they can become 3 distorted further. 4 MR. HUTCHINSON: Move to strike as 5 nonresponsive. 6 BY MR. ANDERSON: 7 Q. And what happens when a nerve is 8 distorted? 9 A. It produces pain. 10 Q. Do you have an opinion to a 11 reasonable degree of medical certainty as to the 12 condition of the nerves that we see here in 13 plaintiff's 4(I), (J), (K), (L) and (M)? 14 A. The nerves themselves are normal so 15 they are healthy nerves which can conduct healthy 16 pain symptoms -- sensation. So they can conduct 17 pain but the position of them is abnormal. 18 Q. Why do you say that? 19 A. They are in scar tissue inside the 20 mesh or outside of the mesh. It's not normal to 21 have nerves in the scar tissue. Scar tissue is 22 not normal tissue, it is abnormal tissue and it is 23 abnormal to have nerves trapped in the scar 24 tissue.</p>

18 (Pages 66 to 69)

Vladimir Iakovlev, M.D.

Page 70	Page 72
<p>1 Q. Doctor, hypothetically if there is</p> <p>2 testimony during this trial that nerve fibers that</p> <p>3 deliver pain signals to the brain cannot be</p> <p>4 stained with this S100 staining that you've been</p> <p>5 showing to the jury would you have an opinion</p> <p>6 about that?</p> <p>7 A. I would.</p> <p>8 Q. And what is that opinion, and have</p> <p>9 you brought anything to help demonstrate that to</p> <p>10 the jury?</p> <p>11 A. My opinion is that it doesn't matter</p> <p>12 for the purpose of my opinions, and generally for</p> <p>13 the analysis of the specimen, and I explain you</p> <p>14 why.</p> <p>15 Q. Have you brought something to</p> <p>16 demonstrate to the jury?</p> <p>17 A. I brought a demonstrative image.</p> <p>18 Q. And do you believe it would be</p> <p>19 helpful to the jury in order to explain your</p> <p>20 conclusions in this regard?</p> <p>21 A. Yes, I do.</p> <p>22 Q. I'm handing you what has been marked</p> <p>23 as Exhibit 5.</p> <p>24 ---PLAINTIFF EXHIBIT NO. 5: Diagram</p>	<p>1 list. Note my objection for the record.</p> <p>2 MR. ANDERSON: And it is a demonstrative</p> <p>3 aid used for purposes of the record, like we</p> <p>4 normally do for trials in using demonstrative</p> <p>5 aids.</p> <p>6 BY MR. ANDERSON:</p> <p>7 Q. So go right ahead. And would you</p> <p>8 like to compare this to the S100 stain?</p> <p>9 A. Yes.</p> <p>10 Q. Please put up that S100. If you</p> <p>11 could put that up next to the nerve.</p> <p>12 A. I'll do it myself.</p> <p>13 Q. Please explain to the jury why you</p> <p>14 have put the S100 stain from Ms. Ramirez next to</p> <p>15 demonstrative aid on the left?</p> <p>16 A. So you can see that there is</p> <p>17 staining in some of the fibers but there's no</p> <p>18 staining in other fibers, but they are all</p> <p>19 together. So all those dark blue nuclei or dots,</p> <p>20 and some of them are staining brown some of them</p> <p>21 are not staining brown. But it doesn't matter,</p> <p>22 they are all together. Motor fibers, sensory</p> <p>23 fibers they are all together in one nerve.</p> <p>24 Q. What is that significant to your</p>
Page 71	Page 73
<p>1 depicting the spinal cord.</p> <p>2 THE DEPONENT: Thank you.</p> <p>3 BY MR. ANDERSON:</p> <p>4 Q. Doctor, please identify that for the</p> <p>5 record.</p> <p>6 A. This is a diagram showing spinal</p> <p>7 cord, so this would be person lying down, facing</p> <p>8 down and this would be the back of the person and</p> <p>9 this is spinal cord. And these are nerves which</p> <p>10 are coming out of spinal cord. And as I explain</p> <p>11 you earlier, the nerves combine multiple wires or</p> <p>12 multiple nerve fibers. Some of the fibers are</p> <p>13 insulated so some are myelinated. And S100 stain</p> <p>14 stains this insulation, it doesn't stain the fiber</p> <p>15 itself or the wire itself but it stains</p> <p>16 insulation. Some of the nerve fibers are not</p> <p>17 insulated but they run in the same bundle. And</p> <p>18 all of them run together insulated, or myelinated,</p> <p>19 S100 positive or S100 negative, all of them run</p> <p>20 together. And I can show you how it's similar to</p> <p>21 what I saw in Ms. Ramirez's body.</p> <p>22 MR. HUTCHINSON: Excuse me. Note my</p> <p>23 objection for the record. This document is not in</p> <p>24 Ms. Ramirez's report, it's not in his reliance</p>	<p>1 opinions, if at all, with regard to whether or not</p> <p>2 S100 can stain sensory nerves?</p> <p>3 A. It doesn't matter, as I said. They</p> <p>4 are all together in one fiber. If S100 stains</p> <p>5 other nerve fibers not those which conduct pain</p> <p>6 they're still there in one bundle.</p> <p>7 MR. ANDERSON: Okay. We need to take a</p> <p>8 break.</p> <p>9 THE VIDEOGRAPHER: Going off the record</p> <p>10 at 10:27 a.m.</p> <p>11 --- Break taken.</p> <p>12 THE VIDEOGRAPHER: We're back on the</p> <p>13 record at 10:37 a.m.</p> <p>14 BY MR. ANDERSON:</p> <p>15 Q. Okay. Doctor, going back to this</p> <p>16 overlaid image that we were showing the jury a</p> <p>17 minute ago where we had the blue staining over the</p> <p>18 top of Exhibit 5?</p> <p>19 A. Yes.</p> <p>20 Q. Do you remember this? So just to be</p> <p>21 clear, I may have misspoken. What type of</p> <p>22 staining is the image on the right?</p> <p>23 A. So right now this is S100 stain.</p> <p>24 Previously we saw neurofilament stain, this is</p>

19 (Pages 70 to 73)



Vladimir Iakovlev, M.D.

<p style="text-align: right;">Page 74</p> <p>1 S100 stain. And if I can have my mouse back. So</p> <p>2 now we have some staining here and some fibers are</p> <p>3 not staining.</p> <p>4 Q. Okay.</p> <p>5 A. Exactly what happens in the diagram.</p> <p>6 Some fibers are myelinated, or insulated, they</p> <p>7 stain with S100 some fibers are not. Pain can be</p> <p>8 delivered by either myelinated or nonmyelinated.</p> <p>9 There are two main type of fibers which deliver</p> <p>10 pain, but again it doesn't matter. All of them</p> <p>11 are bundled together in one nerve. Its' a mixed</p> <p>12 nerve, sensory and motor. If we see a nerve there</p> <p>13 will be sensory fibers, there will be fibers which</p> <p>14 deliver pain signals to the brain.</p> <p>15 Q. Thank you.</p> <p>16 MR. HUTCHINSON: Move to strike as</p> <p>17 nonresponsive.</p> <p>18 BY MR. ANDERSON:</p> <p>19 Q. All of the things that you just</p> <p>20 mentioned to the jury do you hold those to a</p> <p>21 reasonable degree of medical certainty?</p> <p>22 A. Yes, I do.</p> <p>23 Q. Doctor, I'd like to discuss your</p> <p>24 findings regarding your pathological analysis of</p>	<p style="text-align: right;">Page 76</p> <p>1 BY MR. ANDERSON:</p> <p>2 Q. Exhibit 6 identified and used for</p> <p>3 demonstrative purposes only. Can you please</p> <p>4 identify this for the jury?</p> <p>5 A. This is a diagram I prepared in my</p> <p>6 expert report to show the relationship of the</p> <p>7 excised pieces to the anatomical structures in</p> <p>8 Ms. Ramirez's body. So she had --</p> <p>9 Q. Explain what we're seeing in the</p> <p>10 upper photo please?</p> <p>11 A. She had implantation of TVT-O sling</p> <p>12 in September 2010 and it's colored yellow. These</p> <p>13 red triangles on the left, this would be</p> <p>14 Ms. Ramirez's left, our right. And this would be</p> <p>15 Ms. Ramirez's right. These triangles are muscle</p> <p>16 behind the bone, or spaces within the</p> <p>17 transobturator space. And this separate of the</p> <p>18 sling is the part which is exposed or can be found</p> <p>19 if we do dissection. And this is relationship of</p> <p>20 the sling to the urethra. So it was under the</p> <p>21 urethra. We know what happened. By November of</p> <p>22 2010 the left side became painful. It was</p> <p>23 described as bow stringing.</p> <p>24 Q. Is that where you have your cursor</p>
<p style="text-align: right;">Page 75</p> <p>1 Ms. Ramirez's urinary symptoms, okay?</p> <p>2 A. Okay.</p> <p>3 Q. From you review of Ms. Ramirez's</p> <p>4 medical records could you determine which parts of</p> <p>5 the TVT-O sling were explanted and sent to</p> <p>6 pathology from her 2010 and 2015 explant</p> <p>7 surgeries?</p> <p>8 A. Yes. I could correlate operative</p> <p>9 reports, pathological descriptions and my</p> <p>10 examination of the specimen.</p> <p>11 Q. Did you, with my help, prepare a</p> <p>12 demonstrative slide in order to demonstrate these</p> <p>13 explants from these two surgeries?</p> <p>14 A. Yes, I did.</p> <p>15 Q. Do you believe they would be helpful</p> <p>16 to the jury in expressing your opinions?</p> <p>17 A. Yes, I do.</p> <p>18 Q. Would you please show Exhibit 6?</p> <p>19 ---PLAINTIFF EXHIBIT NO. 6: Diagram</p> <p>20 prepared by Dr. Iakovlev depicting the</p> <p>21 relationship of the excised pieces to</p> <p>22 the anatomical structures in Ms.</p> <p>23 Jennifer Ramirez's body.</p> <p>24</p>	<p style="text-align: right;">Page 77</p> <p>1 pointed right now?</p> <p>2 A. Yes. So this is Ms. Ramirez's left.</p> <p>3 The decision at that time was to excise that part</p> <p>4 of sling and release the pressure. And we know</p> <p>5 why that pressure occurred or the tensioning</p> <p>6 occurred.</p> <p>7 Q. And why was that, Doctor?</p> <p>8 A. I explained to you the sling roped</p> <p>9 up; it became filled with dense scar tissue; scar</p> <p>10 tissue contracted, pulled it together, tightened</p> <p>11 it so that bow stringing was at the roped mesh</p> <p>12 contracted because of scar contraction.</p> <p>13 Q. Is that in the area where you're</p> <p>14 showing in the second slide, is that what you're</p> <p>15 talking about?</p> <p>16 A. Yes. And this area was excised,</p> <p>17 partially excised, only 1 centimeter was excised</p> <p>18 in 2010.</p> <p>19 Q. Were you able to look at the piece</p> <p>20 that was excised in 2010 from Ms. Ramirez's body?</p> <p>21 A. No. As far as I understand it was</p> <p>22 not preserved.</p> <p>23 Q. And what are we seeing now in the</p> <p>24 lower image?</p>

20 (Pages 74 to 77)

Vladimir Iakovlev, M.D.

Page 78	Page 80
<p>1 A. So Ms. Ramirez continued to have</p> <p>2 symptoms and in 2015, in March of 2015 two</p> <p>3 portions were excised. And you can see here that</p> <p>4 one portion was still a portion of the left side.</p> <p>5 Q. And what is that little orange dash</p> <p>6 that's going down underneath the urethra, there?</p> <p>7 A. This is the middle portion and it</p> <p>8 identifies which side is left and which side is</p> <p>9 right. So this side was still from the area which</p> <p>10 was described as bow stringing or cording. And we</p> <p>11 can see that one piece during gross examination</p> <p>12 was roped up. So this correlates with the left</p> <p>13 side which was found clinically roped.</p> <p>14 Q. Now, Doctor, are you in this picture</p> <p>15 trying to suggest what Jennifer's urethra actually</p> <p>16 looked like?</p> <p>17 A. No, I just show where the position</p> <p>18 is.</p> <p>19 Q. Okay.</p> <p>20 A. So we agreed that pain was here</p> <p>21 because of tightening of the sling contraction.</p> <p>22 And when it was tightening it was compressing into</p> <p>23 the urethra.</p> <p>24 Q. So on the bottom image where it</p>	<p>1 meshes implanted in the human body, like the TVT-O</p> <p>2 device that was implanted in Ms. Ramirez, what</p> <p>3 does the term degradation mean to you as a</p> <p>4 scientist and pathologist?</p> <p>5 A. The term of degradation, in</p> <p>6 relationship to implanted transvaginal meshes,</p> <p>7 means that the material of the mesh changes,</p> <p>8 changes because the body is attacking it. It's</p> <p>9 trying to destroy or degrade it. So it's intended</p> <p>10 purpose of the inflammatory response to degrade it</p> <p>11 and that's what happens to polypropylene. It</p> <p>12 changes, it degrades.</p> <p>13 Q. Did you make any microphotographs</p> <p>14 from the slides in order to demonstrate this</p> <p>15 principle of degradation from Ms. Ramirez's</p> <p>16 explant that you brought here to show the jury</p> <p>17 today?</p> <p>18 A. Yes, I did.</p> <p>19 Q. Can we see Exhibit 7(A) and (B)</p> <p>20 please.</p> <p>21 ---PLAINTIFF EXHIBIT NO. 7(A) to 7(D):</p> <p>22 Series of high magnification images</p> <p>23 depicting the specimen from Mr. Ramirez</p> <p>24 excised in March 2015.</p>
Page 79	Page 81
<p>1 says, "Excised in two portions", please explain</p> <p>2 that diagram.</p> <p>3 A. So when the remaining part was</p> <p>4 excised in 2015, which was still held by scar</p> <p>5 tissue on the left, the urethra was opened up so</p> <p>6 the pressure on urethra was released. The</p> <p>7 pressure which was caused by the contracted mesh</p> <p>8 was released.</p> <p>9 Q. And are those two excised portions</p> <p>10 the ones that you showed the jury just a few</p> <p>11 moments ago?</p> <p>12 A. Yes.</p> <p>13 Q. And were you able to analyze those</p> <p>14 and those are the slides that you have here today?</p> <p>15 A. Yes, you saw all the images which</p> <p>16 were coming out from these two pieces.</p> <p>17 Q. Okay. You can take that down.</p> <p>18 A. Yes.</p> <p>19 Q. And let's shift gears now, Doctor,</p> <p>20 and discuss something -- a scientific principle</p> <p>21 known as "degradation". Are you familiar with</p> <p>22 that term?</p> <p>23 A. Yes, I am.</p> <p>24 Q. In the context of polypropylene</p>	<p>1 BY MR. ANDERSON:</p> <p>2 Q. And I've marked these as a document</p> <p>3 set which are 7(A) through 7(D).</p> <p>4 Please identify just broadly what we</p> <p>5 have in 7(A) through (D) and then we'll go to the</p> <p>6 two images, 7(A) and (B).</p> <p>7 A. These are high-magnification images</p> <p>8 of the same specimens as we saw before.</p> <p>9 Q. Did you make these?</p> <p>10 A. Yes. I made them using high-power</p> <p>11 objectives.</p> <p>12 Q. Okay.</p> <p>13 A. And this is the same specimen of</p> <p>14 Ms. Ramirez's TVT-O which was excised in March</p> <p>15 2015.</p> <p>16 Q. Please explain to the jury what</p> <p>17 we're seeing in images 7(A) and 7(B)?</p> <p>18 A. The images are focusing on one mesh</p> <p>19 fiber. And as you saw earlier some mesh fibers</p> <p>20 are clear, some mesh fibers are blue.</p> <p>21 Q. What's that blue area there?</p> <p>22 A. This one is blue because, as I said,</p> <p>23 if polypropylene is not colored it's clear, it's</p> <p>24 like fishing line. It's hard to see. So Ethicon</p>

21 (Pages 78 to 81)



Vladimir Iakovlev, M.D.

Page 82	Page 84
<p>1 introduced blue granules into it so it's easier to  2 see in the tissue. It's like colored fishing  3 line. And the dye, which colors it blue, is in  4 granules. And all those granules are introduced  5 into polypropylene by Ethicon when the meshes are  6 manufactured.  7 Q. So just to orient the jury, is this  8 like taking a slice of the fiber?  9 A. I brought something to demonstrate  10 how we slice the fibers in a histology section.  11 Q. Do you think it would be helpful to  12 the jury?  13 A. It will.  14 Q. And is it significant to your  15 opinions?  16 A. Yes, it is.  17 Q. Okay. Tell us what you have,  18 Doctor?  19 A. If we imagine that a mesh fiber is a  20 tree trunk. And we cut mesh fibers the same way  21 as we would cut a tree with a chain saw. But if  22 we take a slice, like a slice of bread but we take  23 slice it with chain saw we would produce something  24 like, a slice of tree trunk. That's exactly what</p>	<p>1 arrow is?  2 A. Because histological dyes can stay  3 inside all these cracks. They can attach inside  4 those cavities and cracks and they can stain  5 purple. But the central part, the central core is  6 solid so histological dyes cannot attach to it  7 that's why it stays clear.  8 Q. Okay. If you can put that down.  9 Did you do anything else to rule out that this  10 outer layer of bark is or is not polypropylene?  11 A. Well, first of all I looked at the  12 granules. You can see the blue granules are in  13 polypropylene. And that was intention of Ethicon,  14 put blue granules to see where polypropylene is.  15 The same thing happens in the microscope. You see  16 blue granules it's polypropylene. And you see  17 blue granules in the purple area and it's also in  18 the bark which is separated. So you cannot  19 explain those blue granules by overlap of this  20 layer with the central core. It's separated but  21 still has the blue granules.  22 Q. Did you use any other type of  23 pathological technique in order to rule out  24 whether there is polypropylene?</p>
Page 83	Page 85
<p>1 happens in the images.  2 Q. So explain how that relates to the  3 images please?  4 A. Now, when the tree grows there is  5 central core of the tree trunk, but then the  6 exposed surface changes because it is exposed to  7 environment. The trees grow bark, so this is the  8 bark of the tree. It's the same wood but it's  9 changing, it's adapting to whatever is outside.  10 There are some cracks and crevices and some  11 cavities in the bark, the same wood but looks  12 slightly different. It can peel off as well. The  13 same happens in the body with polypropylene  14 fibers.  15 Q. And what is that cracked -- that  16 outer layer that we're looking at there? In the  17 bottom end it says "degradation layer". Explain  18 that and these arrows at the bottom please.  19 A. So the central core, like core of  20 the tree trunk is not degraded, it's not bark yet.  21 But the outer layer of polypropylene degrades,  22 it's like bark on the tree. And because it has  23 all these cavities it can be stained.  24 Q. Why is it purple there were the</p>	<p>1 A. I used polarized light, as I  2 mentioned earlier.  3 Q. Explain to the jury briefly what  4 polarized light is.  5 A. Polarized light is a neat technique  6 which was developed a hundred years ago to see  7 foreign bodies in the tissue. Polarizing filters  8 are like polarized sun glasses, there are fine  9 slits in them so they limit the amount of light to  10 specific orientation.  11 Q. Did you take pictures in polarized  12 light of the same mesh fiber that you showed us  13 earlier?  14 A. Yes, I did.  15 Q. Showing you Exhibits 7(C) and (D).  16 What are we seeing in these images?  17 A. These are exactly the same areas in  18 the microscopic slides of Ms. Ramirez's specimen.  19 I just turned the polarizing filters in the  20 microscope and took photograph. And you can see  21 in polarized light both the nondegraded part and  22 the degraded bark are bright compared with the  23 collagen in all other proteins of the body which  24 are much darker in the body.</p>

22 (Pages 82 to 85)

Vladimir Iakovlev, M.D.

Page 86	Page 88
<p>1 Q. Is there a name for that? You said</p> <p>2 "brightness", is there a scientific name for that?</p> <p>3 A. The scientific name for that is</p> <p>4 "birefringence".</p> <p>5 Q. Let's just stick with brightness</p> <p>6 then.</p> <p>7 A. Brightness, okay.</p> <p>8 Q. Go ahead.</p> <p>9 A. And you can see that the bark, you</p> <p>10 can even easier the cracks in the bark. It's</p> <p>11 peeling off and it's cracking. And it's the same</p> <p>12 polypropylene because it's bright, birefringent.</p> <p>13 It has the same blue granules as the core and it's</p> <p>14 very different from all proteins which are</p> <p>15 surrounding the mesh fibers.</p> <p>16 MR. HUTCHINSON: Move to strike as</p> <p>17 nonresponsive.</p> <p>18 BY MR. ANDERSON:</p> <p>19 Q. Doctor, before we were talking about</p> <p>20 the birefringence or the brightness of the outer</p> <p>21 layer.</p> <p>22 A. Yes.</p> <p>23 Q. Can you explain what the</p> <p>24 significance is of this brightness and this outer</p>	<p>1 A. Yes, I can do it.</p> <p>2 Q. Okay, let's do that.</p> <p>3 A. This is how it looks from the</p> <p>4 microscope. I will focus. This is H&amp;E stained</p> <p>5 slide of Ms. Ramirez's specimen which was taken in</p> <p>6 March 2015. This pink color is scar tissue, and</p> <p>7 this blue part, partially folded and displaced,</p> <p>8 the central core of the mesh fiber. Because when</p> <p>9 the knife of microtome slices it to make the</p> <p>10 slices it pushes them away, pushes the central</p> <p>11 part of the fibers away so they get displaced.</p> <p>12 Q. Okay. Now let's see what it looks</p> <p>13 like using the polarizing filters if you would</p> <p>14 please?</p> <p>15 A. Now I will take the polarizing</p> <p>16 filter and I will turn it inside the microscope.</p> <p>17 And when I turn it you can see that the bright</p> <p>18 parts are polypropylene. And the central core,</p> <p>19 which is displaced, is bright here, and the bark,</p> <p>20 because it has all these cracks, is attached to</p> <p>21 the tissue. Collagen anchors to it and holds it</p> <p>22 in the tissue and it stays close to the tissue,</p> <p>23 and you can see the cracks of the degradation</p> <p>24 bark. But you can see how dark are the proteins.</p>
Page 87	Page 89
<p>1 layer displayed in 7(D) where the arrows are?</p> <p>2 A. The significance is that the bright</p> <p>3 parts in the image indicate polypropylene. Both</p> <p>4 the nondegraded core of the fiber is bright and</p> <p>5 the bark is bright and both are made of</p> <p>6 polypropylene. The only difference is the bark is</p> <p>7 degraded polypropylene and the central part is</p> <p>8 nondegraded.</p> <p>9 Q. Doctor, have you reviewed the</p> <p>10 scientific literature regarding the degradation of</p> <p>11 polypropylene in human beings?</p> <p>12 A. Yes, I did.</p> <p>13 Q. And have you published in the</p> <p>14 literature, scientific literature amongst your</p> <p>15 peers about the degradation of polypropylene in</p> <p>16 the human body?</p> <p>17 A. Yes.</p> <p>18 Q. Is -- have you used the microscope</p> <p>19 in order to come up with these images that we just</p> <p>20 saw?</p> <p>21 A. Yes.</p> <p>22 Q. Can you just take one of the -- one</p> <p>23 of the images and put it on there and let's take a</p> <p>24 look and see what's that's like for the jury?</p>	<p>1 All proteins of the human body are dark. The only</p> <p>2 bright part or birefringent parts are</p> <p>3 polypropylene.</p> <p>4 Q. Okay. You can take that down.</p> <p>5 Is there a body of scientific literature</p> <p>6 that's been published about polypropylene</p> <p>7 degradation, including polypropylene sutures?</p> <p>8 A. Yes.</p> <p>9 Q. Have you reviewed medical literature</p> <p>10 from other doctors, pathologists, scientists and</p> <p>11 biomaterials experts who have published</p> <p>12 peer-reviewed literature on the subject of</p> <p>13 polypropylene degradation in the human body?</p> <p>14 A. Yes, I have.</p> <p>15 Q. Have you reviewed as much of this</p> <p>16 published literature about degradation of</p> <p>17 polypropylene mesh as possible?</p> <p>18 A. I try to review everything I could</p> <p>19 find in publically available sources.</p> <p>20 Q. Rather than go through them all have</p> <p>21 you helped me prepare some slides of the studies</p> <p>22 that you find particularly relevant to your</p> <p>23 opinions regarding degradation of transvaginal</p> <p>24 meshes?</p>

Vladimir Iakovlev, M.D.

Page 90	Page 92
<p>1 A. Yes, I did.</p> <p>2 Q. Before we get into those slides,</p> <p>3 Doctor, I'm handing you what has been marked as</p> <p>4 plaintiff's Exhibit 8.</p> <p>5 ---PLAINTIFF EXHIBIT NO. 8: Article</p> <p>6 titled "Comparison of the In Vivo</p> <p>7 Behavior of Polyvinylidene Fluoride and</p> <p>8 Polypropylene Sutures Used in Vascular</p> <p>9 Surgery", found in OSAIO Journal 1998.</p> <p>10 Bates labelled ETH.MESH.05845592 to</p> <p>11 ETH.MESH05845599.</p> <p>12 BY MR. ANDERSON:</p> <p>13 Q. Can you tell us what this is?</p> <p>14 A. This is an article.</p> <p>15 Q. From what journal?</p> <p>16 A. Published from ASAIO Journal.</p> <p>17 Q. Okay. And what year was it</p> <p>18 published?</p> <p>19 A. It was published in 1998.</p> <p>20 Q. Who is the lead author?</p> <p>21 A. The lead author is Celine Mary.</p> <p>22 Q. And was this article peer reviewed?</p> <p>23 A. Yes, it is peer reviewed.</p> <p>24 Q. Did you read and review this article</p>	<p>1 A. It was published in 2003.</p> <p>2 Q. Who is the lead author?</p> <p>3 A. The lead author is Coda.</p> <p>4 Q. And is this article peer reviewed?</p> <p>5 A. Yes, it is.</p> <p>6 Q. Did you review and read this article</p> <p>7 in forming the opinions you're giving here today?</p> <p>8 A. Yes, I did.</p> <p>9 Q. Is this a recognized and reliable</p> <p>10 publication for doctors in your field?</p> <p>11 A. Yes, it is.</p> <p>12 Q. Do experts in your field customarily</p> <p>13 rely on this type of journal in forming medical</p> <p>14 and scientific opinions?</p> <p>15 A. Yes, they do.</p> <p>16 Q. Did they rely on it in forming your</p> <p>17 opinions that you're giving here today?</p> <p>18 A. Yes, I did.</p> <p>19 Q. And now I'll hand you plaintiff's</p> <p>20 Exhibit 10.</p> <p>21 ---PLAINTIFF EXHIBIT NO. 10: Article</p> <p>22 titled "Materials Characterization of</p> <p>23 Explanted Polypropylene Hernia Meshes"</p> <p>24 found in the Journal of Biomedical</p>
Page 91	Page 93
<p>1 in forming the opinions that you're giving here</p> <p>2 today?</p> <p>3 A. Yes, I did.</p> <p>4 Q. Is this a recognized and reliable</p> <p>5 publications for doctors in your field?</p> <p>6 A. Yes, it is.</p> <p>7 Q. Do experts in your field customarily</p> <p>8 rely on this type of journal in forming medical</p> <p>9 and scientific opinions?</p> <p>10 A. Yes, they do.</p> <p>11 Q. And did you rely on it in forming</p> <p>12 the opinions that you're giving here today?</p> <p>13 A. Yes, I did.</p> <p>14 Q. Showing you what we'll mark as</p> <p>15 plaintiff's Exhibit 9.</p> <p>16 ---PLAINTIFF EXHIBIT NO. 9: Article</p> <p>17 titled "Structural alterations of</p> <p>18 prosthetic meshes in humans" found in</p> <p>19 Hernia Journal, 2003.</p> <p>20 BY MR. ANDERSON:</p> <p>21 Q. Can you please identify the journal</p> <p>22 from which plaintiff's Exhibit 9 comes?</p> <p>23 A. This is Hernia Journal.</p> <p>24 Q. Okay. And was it published?</p>	<p>1 Materials Research Part B: Applied</p> <p>2 Biomaterials.</p> <p>3 BY MR. ANDERSON:</p> <p>4 Q. Was this published?</p> <p>5 A. It was published in --</p> <p>6 Q. Was it published?</p> <p>7 A. It was published.</p> <p>8 Q. In what journal?</p> <p>9 A. Journal of Biomedical Materials</p> <p>10 Research Part B: Applied Biomaterials.</p> <p>11 Q. What year?</p> <p>12 A. It was published in 2007.</p> <p>13 Q. Was this article peer reviewed?</p> <p>14 A. Yes, it is.</p> <p>15 Q. Who's the lead author?</p> <p>16 A. Lead author is Costello.</p> <p>17 Q. Did you read and review this article</p> <p>18 in forming the opinions that you're giving here</p> <p>19 today?</p> <p>20 A. Yes, I did.</p> <p>21 Q. Is this a recognized and reliable</p> <p>22 publication for doctors in your field?</p> <p>23 A. Yes, it is.</p> <p>24 Q. Do experts in your field customarily</p>

24 (Pages 90 to 93)

Vladimir Iakovlev, M.D.

Page 94	Page 96
<p>1 rely on this type of journal in forming medical</p> <p>2 and scientific opinions?</p> <p>3 A. Yes, they do.</p> <p>4 Q. Did you rely on it in forming the</p> <p>5 opinions you're giving here today?</p> <p>6 A. Yes I did.</p> <p>7 Q. Showing you what's been marked as</p> <p>8 plaintiff's Exhibit 11.</p> <p>9 ---PLAINTIFF EXHIBIT NO. 11: Article</p> <p>10 titled "Materials characterization of</p> <p>11 explanted polypropylene, polyethylene</p> <p>12 terephthalate, and expanded</p> <p>13 polytetrafluoroethylene composites:</p> <p>14 Spectral and thermal analysis", found</p> <p>15 in Journal of Biomedical Materials</p> <p>16 Research Part B: Applied Biomaterials.</p> <p>17 BY MR. ANDERSON:</p> <p>18 Q. Was this article published?</p> <p>19 A. Yes, it was.</p> <p>20 Q. And what journal was it published</p> <p>21 in?</p> <p>22 A. Journal of Biomedical Materials and</p> <p>23 Research B: Applied Biomaterials.</p> <p>24 Q. What year was it published?</p>	<p>1 Hernia Repair: A Comprehensive Analysis</p> <p>2 of Select Commercial Devices", found in</p> <p>3 MDPI Materials, 2015.</p> <p>4 BY MR. ANDERSON:</p> <p>5 Q. Was Exhibit 12 published?</p> <p>6 A. Yes, it was.</p> <p>7 Q. In what journal?</p> <p>8 A. MDPI Materials.</p> <p>9 Q. And what year was it published?</p> <p>10 A. It was published in 2015.</p> <p>11 Q. What is the lead author?</p> <p>12 A. Lead author is Miao.</p> <p>13 Q. And was this article peer reviewed?</p> <p>14 A. It was.</p> <p>15 Q. Did you review and read this article</p> <p>16 in forming the opinions that you're giving here</p> <p>17 today?</p> <p>18 A. Yes, I did.</p> <p>19 Q. Is this a recognized and reliable</p> <p>20 publication for doctors in your field?</p> <p>21 A. Yes, it is.</p> <p>22 Q. Do experts in your field customarily</p> <p>23 rely on this type of journal in forming medical</p> <p>24 and scientific opinions?</p>
Page 95	Page 97
<p>1 A. It was published in 2010.</p> <p>2 Q. Who is the lead author?</p> <p>3 A. Lead author is Cozad.</p> <p>4 Q. Is this article peer reviewed?</p> <p>5 A. Yes, it is.</p> <p>6 Q. Did you read and review this article</p> <p>7 in forming the opinions that you are giving here</p> <p>8 today?</p> <p>9 A. Yes, I did.</p> <p>10 Q. Is this a recognized and reliable</p> <p>11 publication for doctors in your field?</p> <p>12 A. Yes, it is.</p> <p>13 Q. Do experts in your field customarily</p> <p>14 rely on this type of journal in forming medical</p> <p>15 and scientific opinions?</p> <p>16 A. Yes, they do.</p> <p>17 Q. Did you rely on it in forming the</p> <p>18 opinions you are giving here today?</p> <p>19 A. Yes, I do.</p> <p>20 Q. Marking plaintiff's Exhibit 12 for</p> <p>21 identification.</p> <p>22 ---PLAINTIFF EXHIBIT NO. 12: Article</p> <p>23 titled "Physical Characteristics of</p> <p>24 Medical Textile Prostheses Designed for</p>	<p>1 A. Yes, they do.</p> <p>2 Q. Did you rely on it in forming the</p> <p>3 opinions you are giving here today?</p> <p>4 A. Yes, I did.</p> <p>5 Q. Showing you what's been marked as</p> <p>6 plaintiff's Exhibit 13.</p> <p>7 ---PLAINTIFF EXHIBIT NO. 13: Article</p> <p>8 titled "Degradation of polypropylene in</p> <p>9 the human eye: A sem-study", found in</p> <p>10 Documenta Ophthalmologica, 1986.</p> <p>11 BY MR. ANDERSON:</p> <p>12 Q. Can you please identify whether this</p> <p>13 article was published?</p> <p>14 A. It was published.</p> <p>15 Q. In what journal?</p> <p>16 A. Documenta Ophthalmologica.</p> <p>17 Q. And who is the lead author?</p> <p>18 A. Lead author is Jogenbloed.</p> <p>19 Q. And what year was it published?</p> <p>20 A. 1986.</p> <p>21 Q. And is this article peer reviewed?</p> <p>22 A. Yes, it is.</p> <p>23 Q. Did you read and review this article</p> <p>24 in forming the opinions that you are giving here</p>

25 (Pages 94 to 97)

Vladimir Iakovlev, M.D.

Page 98	Page 100
<p>1 today?</p> <p>2 A. Yes, I did.</p> <p>3 Q. Is this a recognized and reliable</p> <p>4 publication for doctors in your field?</p> <p>5 A. Yes, it is.</p> <p>6 Q. Do experts in your field customarily</p> <p>7 rely on this type of journal in forming medical</p> <p>8 and scientific opinions?</p> <p>9 A. Yes, they do.</p> <p>10 Q. Did you rely on it in forming the</p> <p>11 opinions you are giving here today?</p> <p>12 A. Yes, I did.</p> <p>13 Q. Showing you what has been marked as</p> <p>14 Exhibit 14.</p> <p>15 ---PLAINTIFF EXHIBIT NO. 14: Article</p> <p>16 titled "Reinforcement Materials in Soft</p> <p>17 Tissue Repair: Key Parameters</p> <p>18 Controlling Tolerance and Performance -</p> <p>19 Current and Future Trends in Mesh</p> <p>20 Development", found in the journal New</p> <p>21 Techniques in Genital Prolapse Surgery,</p> <p>22 2011.</p> <p>23 BY MR. ANDERSON:</p> <p>24 Q. Was this article published?</p>	<p>1 opinions that you are giving here today?</p> <p>2 A. Yes, I did.</p> <p>3 Q. Showing you what has been marked as</p> <p>4 plaintiff's Exhibit 15.</p> <p>5 ---PLAINTIFF EXHIBIT NO. 15: Article</p> <p>6 titled "Subcutaneous Implants of</p> <p>7 Polypropylene Filaments", found in the</p> <p>8 Journal of Biomedical Material</p> <p>9 Research, 1976.</p> <p>10 BY MR. ANDERSON:</p> <p>11 Q. Was this article published?</p> <p>12 A. Yes, it was.</p> <p>13 Q. And what article -- I'm sorry, what</p> <p>14 journal was it published in?</p> <p>15 A. Journal of Biomedical Material</p> <p>16 Research.</p> <p>17 Q. What year was it published?</p> <p>18 A. 1976.</p> <p>19 Q. And who is the lead author in this</p> <p>20 publication?</p> <p>21 A. Leibert.</p> <p>22 Q. Is this article peer reviewed?</p> <p>23 A. Yes, it is.</p> <p>24 Q. Did you read and review this article</p>
Page 99	Page 101
<p>1 A. It was.</p> <p>2 Q. And in what journal was it</p> <p>3 published? Bottom of the page.</p> <p>4 A. New Techniques in Genital Prolapse</p> <p>5 Surgery.</p> <p>6 Q. What year was it published?</p> <p>7 A. It was published in 2011.</p> <p>8 Q. And who is the lead author of this</p> <p>9 publication in Exhibit 14?</p> <p>10 A. Lefranc.</p> <p>11 Q. And is this article peer reviewed?</p> <p>12 A. Yes, it is.</p> <p>13 Q. Is this a recognized and reliable</p> <p>14 publication for doctors in the field?</p> <p>15 A. Yes, it is.</p> <p>16 Q. Did you read and review this article</p> <p>17 in forming the opinions that you're giving here</p> <p>18 today?</p> <p>19 A. Yes, I did.</p> <p>20 Q. Do experts in your field customarily</p> <p>21 rely on this type of journal in forming medical</p> <p>22 and scientific opinions?</p> <p>23 A. Yes, they do.</p> <p>24 Q. Did you rely on it in forming the</p>	<p>1 in forming the opinions that you're giving here</p> <p>2 today?</p> <p>3 A. Yes, I did.</p> <p>4 Q. Is this a recognized and reliable</p> <p>5 publication for doctors in your field?</p> <p>6 A. Yes, it is.</p> <p>7 Q. Do experts in your field customarily</p> <p>8 rely on this type of journal in forming medical</p> <p>9 and scientific opinions?</p> <p>10 A. Yes, they do.</p> <p>11 Q. Did you rely on it in forming the</p> <p>12 opinions you're giving here today?</p> <p>13 A. Yes, I did.</p> <p>14 Q. Showing you what's been marked as</p> <p>15 plaintiff's Exhibit 16.</p> <p>16 ---PLAINTIFF EXHIBIT NO. 16: Article</p> <p>17 titled "Degradation, infection and heat</p> <p>18 effects on polypropylene mesh for</p> <p>19 pelvic implantation: what was known and</p> <p>20 when it was known", found in the</p> <p>21 International Urogynecology Journal,</p> <p>22 2011.</p> <p>23 BY MR. ANDERSON:</p> <p>24 Q. Was this article published?</p>

26 (Pages 98 to 101)



Vladimir Iakovlev, M.D.

Page 102	Page 104
<p>1 A. Yes, It was.</p> <p>2 Q. In what journal?</p> <p>3 A. International Urogynecology Journal.</p> <p>4 Q. And who is the lead author?</p> <p>5 A. Ostergard.</p> <p>6 Q. Was this peer reviewed?</p> <p>7 A. It was.</p> <p>8 Q. Have you read and reviewed this</p> <p>9 article in forming the opinions that you're giving</p> <p>10 here today?</p> <p>11 A. Yes, I did.</p> <p>12 Q. Is this a recognized and reliable</p> <p>13 publication for doctors in your field?</p> <p>14 A. Yes, it is.</p> <p>15 Q. Do experts in your field customarily</p> <p>16 rely on this type of journal in forming medical</p> <p>17 and scientific opinions?</p> <p>18 A. Yes, they do.</p> <p>19 Q. Did you rely on it in forming the</p> <p>20 opinions that you are giving here today?</p> <p>21 A. Yes, I did.</p> <p>22 Q. Just a few more here, Doctor. I'm</p> <p>23 showing you what has been marked as Exhibit 17.</p> <p>24 ---PLAINTIFF EXHIBIT NO. 17: Article</p>	<p>1 publication for doctors in your field?</p> <p>2 A. Yes, it is.</p> <p>3 Q. Do expert in your field customarily</p> <p>4 rely on this type of journal in forming medical</p> <p>5 and scientific opinions?</p> <p>6 A. Yes, they do.</p> <p>7 Q. Did you rely on it in forming the</p> <p>8 opinions you are giving here today?</p> <p>9 A. Yes, I did.</p> <p>10 Q. I'm showing you what's been marked</p> <p>11 as plaintiff's Exhibit 18.</p> <p>12 ---PLAINTIFF EXHIBIT NO. 18: Article</p> <p>13 titled "Materials characterization and</p> <p>14 histological analysis of explanted</p> <p>15 polypropylene, PTFE, and PET hernia</p> <p>16 meshes from an individual patient",</p> <p>17 found in the Journal of Material</p> <p>18 Medicine, 2013.</p> <p>19 BY MR. ANDERSON:</p> <p>20 Q. Was this article published?</p> <p>21 A. Yes, it was.</p> <p>22 Q. What journal was it published in?</p> <p>23 A. Journal of Material Science,</p> <p>24 Material Medicine.</p>
Page 103	Page 105
<p>1 titled "Post-Implantation alterations</p> <p>2 of Polypropylene in the Human", found</p> <p>3 in The Journal of Urology, 2012.</p> <p>4 BY MR. ANDERSON:</p> <p>5 Q. Was this article published?</p> <p>6 A. Yes, it was.</p> <p>7 Q. And what journal was this article</p> <p>8 published in?</p> <p>9 A. The Journal of Urology.</p> <p>10 Q. And what year was it published?</p> <p>11 A. It was published in 2012.</p> <p>12 Q. Who is the lead author on this</p> <p>13 publication?</p> <p>14 A. Sternschuss.</p> <p>15 Q. Was this published in a</p> <p>16 peer-reviewed journal?</p> <p>17 A. Yes, it was.</p> <p>18 Q. Was this article peer reviewed?</p> <p>19 A. Yes, it was.</p> <p>20 Q. Did you read and review this article</p> <p>21 in forming the opinions that you are giving here</p> <p>22 today?</p> <p>23 A. Yes, I did.</p> <p>24 Q. Is this a recognized and reliable</p>	<p>1 Q. Was it published -- what year was it</p> <p>2 published?</p> <p>3 A. 2013.</p> <p>4 Q. Who is the lead author?</p> <p>5 A. Wood.</p> <p>6 Q. Is this article peer reviewed?</p> <p>7 A. Yes, it is.</p> <p>8 Q. Did you read and review this article</p> <p>9 in forming the opinions that you are giving here</p> <p>10 today?</p> <p>11 A. Yes, I did.</p> <p>12 Q. Is this a recognized and reliable</p> <p>13 publication for doctors in your field?</p> <p>14 A. Yes, it is.</p> <p>15 Q. Do experts in your field customarily</p> <p>16 rely on this type of journal in forming medical</p> <p>17 and scientific opinions?</p> <p>18 A. Yes, they do.</p> <p>19 Q. Did you rely on it in forming the</p> <p>20 opinions you are giving here today?</p> <p>21 A. Yes, I did.</p> <p>22 Q. I'm showing you what has been marked</p> <p>23 as Exhibit 19.</p> <p>24 ---PLAINTIFF EXHIBIT NO. 19: Article</p>

27 (Pages 102 to 105)

Vladimir Iakovlev, M.D.

Page 106	Page 108
<p>1 titled "Pathology of Explanted 2 Transvaginal Meshes", found in World 3 Academy of Science, Engineering and 4 Technology International Journal of 5 Medical, Health, Pharmaceutical and 6 Biomedical Engineering, 2014. 7 BY MR. ANDERSON: 8 Q. Do you recognize this article? 9 A. Yes, I do. 10 Q. And was it published? 11 A. It was. 12 Q. And in what journal was it 13 published? 14 A. World Academy of Science, 15 Engineering and Technology International Journal 16 of Medical, Health, Pharmaceutical and Biomedical 17 Engineering. 18 Q. And who is the lead author? 19 A. Me. 20 Q. And was this peer reviewed? 21 A. Yes, it was. 22 Q. And did you read and review -- well, 23 are you using this article to form the opinions 24 that you are giving here today?</p>	<p>1 A. It's Biomedical Materials Part B. 2 Q. Journal of Biomaterials Part B? 3 A. Yes. Journal of Biomaterials Part 4 B. 5 Q. Who's the lead author on this? 6 A. Me. 7 Q. And when was it published? 8 A. It was published in 2015. 9 Q. Okay. Was it peer reviewed? 10 A. It was. 11 Q. Did you rely upon this in forming 12 the opinions that you're giving here today? 13 A. Yes, I did. 14 Q. Is it a recognized and reliable 15 publication for doctors in your field? 16 A. Yes, it is. 17 Q. Do experts in your field customarily 18 rely on this type of journal in forming medical 19 and scientific opinions? 20 A. Yes, they do. 21 Q. Did you rely on it in forming the 22 opinions that you're giving here today? 23 A. Yes, I did. 24 Q. Doctor, after looking at all of</p>
Page 107	Page 109
<p>1 A. Yes, I am. 2 Q. Is this a recognized and reliable 3 publication for doctors in your field? 4 A. Yes, it is. 5 Q. Do experts in your field customarily 6 rely on this type of journal in forming medical 7 and scientific opinions? 8 A. Yes, they do. 9 Q. Did you rely on it in forming the 10 opinions you're giving here today? 11 A. Yes, I did. 12 Q. Last but not least, I'm showing you 13 plaintiff's Exhibit 20. 14 ---PLAINTIFF EXHIBIT NO. 20: Article 15 titled, "Degradation of polypropylene 16 in vivo: A microscopic analysis of 17 meshes explanted from patients", found 18 in the Journal of Biomedical Materials 19 Part B, 2015. 20 BY MR. ANDERSON: 21 Q. Was this article published? 22 A. It was. 23 Q. And what journal was it published 24 in?</p>	<p>1 these and identifying the record, please tell us 2 what was significant about all of these articles 3 taken as a whole to the opinions you're expressing 4 here today? 5 MR. HUTCHINSON: Objection. 6 THE DEPONENT: All these articles they 7 show that for decades researchers continue to 8 study polypropylene degradation in the body using 9 different methods starting from 1970's. And their 10 conclusion was always the same, polypropylene 11 degrades in the body. 12 BY MR. ANDERSON: 13 Q. Doctor, have you assisted me in 14 making some slides to demonstrate some of the 15 findings in this literature regarding 16 polypropylene degradation? 17 A. Yes, I did. 18 Q. Okay. And do you think that would 19 be helpful to the jury in this case? 20 A. It would. 21 Q. Is it significant to your opinions? 22 A. It is. 23 Q. If you could pull up Exhibit 21 24 please.</p>

28 (Pages 106 to 109)



Vladimir Iakovlev, M.D.

Page 110	Page 112
<p>1 ---PLAINTIFF EXHIBIT NO. 21: Printout 2 of PowerPoint slides created with the 3 assistance of Dr. Iakovlev for 4 presentation to the jury. 5 BY MR. ANDERSON: 6 Q. Exhibit 21 is a PowerPoint slide. 7 Is this is the presentation that you helped me 8 create for the jury? 9 A. Yes, it is. 10 Q. And if we could pull up the first 11 slide. What is this -- please identify this first 12 slide and tell us whether or not it's significant 13 to your opinions? 14 A. Well, these are headings of some of 15 the articles we just went through. It shows the 16 range of the techniques and repeated conclusions 17 over the last 50 years. 18 Q. Okay. 19 A. Next slide please. 20 Q. Why is this slide significant to 21 your opinions? 22 A. This slide shows one of the first 23 publications showing that polypropylene degrades 24 while implanted in the body. It dates to 1976.</p>	<p>1 them showed the same conclusion that polypropylene 2 degrades in the body. 3 Q. From your review of them can you 4 tell whether or not these are different scientists 5 from different specialties? 6 A. Yes. I can see their affiliations, 7 what they are. Surgeons, bioengineers. I'm a 8 pathologists. Other pathologists were involved. 9 Q. Okay. Next slide. 10 A. And doesn't matter where 11 polypropylene is implanted. In the eye, we saw 12 that some ophthalmological journals were published 13 in. In animals or in humans it still degrades 14 while it's in the body. Doesn't matter what part 15 of the body, it degrades. 16 Q. Okay. Next slide. 17 A. Next slide. And this is the list of 18 authors, I mean, this is part of the people who 19 made the conclusion that polypropylene degrades in 20 the body. And some of them are Ph.D. scientists, 21 some of them are medical doctors, some of them are 22 surgeons, some of them are pathologists like me 23 and some of them are gynecologists. 24 Q. Did you try and compile the entire</p>
Page 111	Page 113
<p>1 And the conclusion was: 2 "Analysis shows that degradation 3 begins to occur after only a few days. 4 Although the reaction sequence is not 5 known several factors suggest that the 6 in vivo degradation process is similar 7 to auto-oxidation which occurs in air 8 or oxygen." 9 And that was in 1976. 10 Q. Okay. Next slide. Let's go back 11 just one second. We've heard this word "in vivo" 12 a couple of times, and the jury has probably heard 13 it by this time, but what does "in vivo" mean, 14 Doctor? 15 A. In vivo means in the body. It can 16 be any body, human body, animal body. In a live 17 body. 18 Q. Okay, next slide please. What is 19 this slide please, Doctor? 20 A. This slide shows a list of the 21 articles we just went through. It shows that 22 there is a range of different journals, people 23 from different countries and continents, different 24 dates, 1986, 2011, 2014, 2003, '98. And all of</p>	<p>1 list of all the scientist and doctors over the 2 last 40 or 50 years who have published on this? 3 A. No, this is just one group. 4 Q. Okay. Next slide. Why do we have 5 this slide, Doctor? 6 A. This is one of the papers, and this 7 is example of the conclusions we see in these 8 papers. In this specific study the authors 9 compared three different mesh materials which were 10 explanted from the same patient and they did 11 side-by-side comparison. "Polypropylene mesh 12 demonstrated chemical degradation via oxidation, 13 permanent distortion of the mesh and changes in 14 thermal properties." 15 Q. Why is that important, Doctor? 16 A. It supports all other papers, all 17 other articles, all other studies and my 18 publications as well. All of those studies they 19 make the same conclusion. 20 Q. Next slide please. Why is this 21 slide significant to your opinions, Doctor? 22 A. This is another example of the 23 conclusion. Another paper, another group of 24 scientists. "Overall the results support our</p>

Vladimir Iakovlev, M.D.

Page 114	Page 116
<p>1 hypothesis that oxidation is involved with the  2 degradation of polypropylene hernia mesh  3 materials."  4 Q. You mentioned your publications.  5 Next slide please. One question, Doctor, you  6 mention in the last article that that was a hernia  7 mesh?  8 A. Yes, it was.  9 Q. From your review of the records,  10 your publications, your review of all of the  11 scientific journals, your presentation at  12 conferences with other scientists and doctors, as  13 well as your examination of over 300 explanted  14 meshes, have you noticed any difference or  15 similarities between explanted hernia  16 polypropylene meshes versus explanted transvaginal  17 meshes?  18 A. In terms of degradation?  19 Q. Yes.  20 A. All of them degrade.  21 Q. Thank you. Now this slide.  22 A. These are my publications where I  23 describe polypropylene degradation which occurs in  24 vivo, and that's what happened in Ms. Ramirez's</p>	<p>1 BY MR. ANDERSON:  2 Q. Doctor, do you have an opinion as to  3 whether or not the mesh that is still in her body  4 is still degrading?  5 A. Yes, I do.  6 Q. And what is that opinion?  7 A. My opinion is that those parts which  8 are left in the body of Ms. Ramirez are still  9 degrading.  10 Q. Doctor, based upon all of the work  11 that you've done and your publications, and your  12 review of all the explanted meshes, do you have an  13 opinion, to a reasonable degree of medical  14 certainty, as to what complications degraded mesh  15 causes in vaginal tissue?  16 A. So the degradation occurs on all  17 surfaces of the mesh fibers. The entire mesh has  18 surface which is covered with degraded  19 polypropylene. All interactions between the body  20 and mesh occur through this degraded layer. From  21 day one after implantation the interactions  22 between the body and the mesh is not through  23 pristine polypropylene, it's always going through  24 this degraded layer.</p>
Page 115	Page 117
<p>1 body.  2 Q. Okay, you can take that down.  3 Doctor, based upon your background,  4 training, experience, based upon your work as a  5 pathologist over these many years, based upon your  6 review of over 300 explanted, polypropylene meshes  7 and over -- over 200 transvaginal meshes,  8 including Ethicon meshes, based upon your  9 publications in the literature, your review of all  10 the publications in the literature, as well as all  11 of the work that you've done in this case, do you  12 have an opinion to a reasonable degree of medical  13 certainty as to whether or not the TVT-O mesh that  14 was implanted in Ms. Ramirez degraded?  15 A. Yes, I do.  16 Q. And what is that opinion?  17 A. My opinion is that TVT-O mesh made  18 out of polypropylene degraded while in the body of  19 Ms. Ramirez and is still degrading. The remaining  20 parts which remain in her body are still  21 degrading.  22 MR. HUTCHINSON: Objection. Move to  23 strike as nonresponsive.  24</p>	<p>1 Q. What's the significance of that?  2 MR. HUTCHINSON: Objection. Move to  3 strike as nonresponsive.  4 BY MR. ANDERSON:  5 Q. Go ahead.  6 A. So all what we see, what happens  7 after, is mediated through this degraded layer.  8 Q. What do you mean by "mediated"  9 through the degraded layer?  10 A. Because all interactions, the  11 sensing of the foreign body, the chemical  12 interactions, the physical interactions are all  13 through this degraded surface. The surface  14 becomes brittle, we saw cracking. So the entire  15 surface, the entire mesh is covered with this  16 crust of brittle, hardened material.  17 Q. And what physical changes have you  18 noted in the brittle, explanted transvaginal  19 meshes?  20 A. It leads to hardening, stiffening,  21 embrittlement of the mesh.  22 Q. In your opinion what does that mean  23 to the patient if there's a hardened and brittle,  24 stiffened mesh in the transvaginal tissues?</p>

30 (Pages 114 to 117)

Vladimir Iakovlev, M.D.

Page 118	Page 120
<p>1 A. So it doesn't stay soft and flexible</p> <p>2 it becomes harder, it becomes stiffer.</p> <p>3 Q. And what does the stiffness mean to</p> <p>4 the patient?</p> <p>5 A. It damages the tissue around it. It</p> <p>6 can damage it easier because it's much stiffer</p> <p>7 than the tissue around it.</p> <p>8 Q. And back to my earlier question. Do</p> <p>9 you have an opinion as to whether or not this</p> <p>10 stiffness, and this rigidity, and this degradation</p> <p>11 in Ms. Ramirez's TVT-O sling caused any of her</p> <p>12 injuries in this case?</p> <p>13 MR. HUTCHINSON: Objection, foundation.</p> <p>14 THE DEPONENT: Yes, I do.</p> <p>15 BY MR. ANDERSON:</p> <p>16 Q. And what injuries do you believe, to</p> <p>17 a reasonable degree of medical certainty the</p> <p>18 degradation caused for Ms. Ramirez?</p> <p>19 A. Well, as I said, all interactions</p> <p>20 between the body and the mesh are going through</p> <p>21 this degraded layer.</p> <p>22 Q. What specific complications as it</p> <p>23 went through that layer did the degraded mesh</p> <p>24 cause or contribute to for Ms. Ramirez?</p>	<p>1 A. Well, first of all I showed you the</p> <p>2 features I saw in the microscope.</p> <p>3 Q. Okay.</p> <p>4 A. The blue granules, the behavior of</p> <p>5 the material in polarized light. This was all</p> <p>6 consistent with the earlier published body of the</p> <p>7 literature that polypropylene degrades in vivo.</p> <p>8 Then I also observed several other features in my</p> <p>9 research.</p> <p>10 Q. What was that?</p> <p>11 A. The first feature I observed that</p> <p>12 the outer layer can be stained with different</p> <p>13 histological dyes.</p> <p>14 Q. What do you mean by that?</p> <p>15 A. Any dye I would use or any stain</p> <p>16 would stain it. It can be red, it can be blue, it</p> <p>17 can be green. There is no difference. If it's</p> <p>18 positively charged dye, negatively charged dye,</p> <p>19 larger molecule size, small, it all stains. It</p> <p>20 stains nonspecifically.</p> <p>21 Q. What do you mean by these stains</p> <p>22 stain the bark layer nonspecifically?</p> <p>23 A. It means that the staining is not</p> <p>24 due to specific electrostatic forces or some other</p>
Page 119	Page 121
<p>1 MR. HUTCHINSON: Same objection,</p> <p>2 foundation.</p> <p>3 THE DEPONENT: Pain, pain on sexual</p> <p>4 intercourse, urinary symptoms.</p> <p>5 BY MR. ANDERSON:</p> <p>6 Q. Do you have an opinion as to whether</p> <p>7 or not what you have depicted in some of these</p> <p>8 images as degraded polypropylene, this cracked</p> <p>9 outer layer or this bark that you described for</p> <p>10 the jury, whether that is biologic material or</p> <p>11 something like protein from the body that changed</p> <p>12 the polypropylene? Do you have an opinion on</p> <p>13 that?</p> <p>14 A. I do.</p> <p>15 Q. And what's that opinion?</p> <p>16 A. My opinion is it is not biological</p> <p>17 material. After conducting several tests and</p> <p>18 observations.</p> <p>19 Q. What tests did you do and what</p> <p>20 observations did you make to rule out whether or</p> <p>21 not the formalin, and other chemicals which are</p> <p>22 used to make the slides in this case, had anything</p> <p>23 to do with the degradation bark in the cracked</p> <p>24 outer layer?</p>	<p>1 specific forces. There is a nonspecific staining</p> <p>2 because of the porosity, because of the cavities</p> <p>3 in the bark layer. However, several stains do not</p> <p>4 stain it.</p> <p>5 Q. What do you mean by that?</p> <p>6 A. And those stains are specifically</p> <p>7 designed to stain proteins. And those stains</p> <p>8 which you saw brown stains they did not stain it.</p> <p>9 There is no protein inside. It does not stain</p> <p>10 with protein stains.</p> <p>11 Q. Did you do anything else to rule out</p> <p>12 whether or not formalin, or any other chemicals</p> <p>13 that are used to prepare the pathological sample</p> <p>14 for the slides, or anything else had anything to</p> <p>15 do with this degraded bark in the cracked outer</p> <p>16 layer?</p> <p>17 A. Yes, I did.</p> <p>18 Q. What did you do?</p> <p>19 A. I took several pieces of pristine</p> <p>20 mesh, put it in formalin for four months, and then</p> <p>21 took it out of formalin and loaded it with other</p> <p>22 specimens through the same processing protocol or</p> <p>23 processing sequence as all other specimens. They</p> <p>24 all went through the same chemicals.</p>

31 (Pages 118 to 121)

Vladimir Iakovlev, M.D.

Page 122	Page 124
<p>1 Q. And what were your findings?</p> <p>2 A. And the findings were that there is</p> <p>3 no degraded layer after four months in formalin</p> <p>4 and exposure to all chemicals to make the slides.</p> <p>5 Q. In your research did you ever have</p> <p>6 an occasion to see any explanted mesh before it</p> <p>7 was put into formalin or before histological</p> <p>8 slides were created?</p> <p>9 A. Yes, I had the chance.</p> <p>10 Q. Please explain that to the jury and</p> <p>11 explain what your findings were.</p> <p>12 A. I was called from OR when the</p> <p>13 excision was done.</p> <p>14 Q. At St. Michael's?</p> <p>15 A. At St. Michael's.</p> <p>16 Q. When you say "OR" do you mean the</p> <p>17 operating room?</p> <p>18 A. Operating room.</p> <p>19 Q. Now explain it slowly so that the</p> <p>20 jury can understand.</p> <p>21 A. The patient had symptoms of pain,</p> <p>22 the sling had to be excised. And when I examined</p> <p>23 it, while it was fresh, while it was not dried</p> <p>24 yet, while it was -- even before it was put in</p>	<p>1 A. Yes. The technique was introduced</p> <p>2 in 1920's to identify sutures, even at that time.</p> <p>3 MR. HUTCHINSON: Objection. Move to</p> <p>4 strike as nonresponsive.</p> <p>5 BY MR. ANDERSON:</p> <p>6 Q. Has it been around since the 1920s,</p> <p>7 Doctor?</p> <p>8 A. Yes, it has.</p> <p>9 Q. Great. Have you seen any</p> <p>10 peer-reviewed publications where they used</p> <p>11 polarized light in these same techniques?</p> <p>12 A. Yes, I did.</p> <p>13 Q. I'm showing you what's been marked</p> <p>14 as plaintiff's Exhibit 22.</p> <p>15 ---PLAINTIFF EXHIBIT NO. 22: Article</p> <p>16 titled "Pathologic Evaluation of</p> <p>17 Explanted Vaginal Mesh:</p> <p>18 Interdisciplinary Experience From a</p> <p>19 Referral Center", found in the Journal</p> <p>20 of Female Pelvic Medicine &amp;</p> <p>21 Reconstructive Surgery, 2013.</p> <p>22 BY MR. ANDERSON:</p> <p>23 Q. You asked me to highlight this</p> <p>24 article for purposes of presentation to the jury?</p>
Page 123	Page 125
<p>1 formalin, some fibers were sticking out. I</p> <p>2 examined it in the microscope and I saw extensive</p> <p>3 cracking.</p> <p>4 Q. And is that -- are the photographs</p> <p>5 of that in your peer-reviewed publications?</p> <p>6 A. Yes, they are.</p> <p>7 Q. Thank you. Did you use standards --</p> <p>8 sorry, strike that.</p> <p>9 Did you use procedures and protocols</p> <p>10 that are standard in your industry to conduct the</p> <p>11 formalin testing on the pristine mesh that had</p> <p>12 never been implanted in the body?</p> <p>13 A. Yes, I did.</p> <p>14 Q. Doctor, with regard to the usage of</p> <p>15 polarized light to assess the mesh explants you</p> <p>16 were showing the jury the thing like you use</p> <p>17 fishing glass lenses a few minutes ago. Do you</p> <p>18 remember that?</p> <p>19 A. Yes, I do.</p> <p>20 Q. Are there other scientist that have</p> <p>21 used this polarization technique in order to</p> <p>22 examine whether or not there's polypropylene mesh</p> <p>23 in tissue samples on microscopic slides like you</p> <p>24 did?</p>	<p>1 A. Yes, I did.</p> <p>2 Q. Is this -- was this article</p> <p>3 published?</p> <p>4 A. Yes, it was.</p> <p>5 Q. What journal was it published in?</p> <p>6 A. Female Pelvic Medicine and</p> <p>7 Reconstructive Surgery.</p> <p>8 Q. In what year?</p> <p>9 A. 2013.</p> <p>10 Q. Who's the lead author?</p> <p>11 A. Smith.</p> <p>12 Q. Was this a peer-reviewed article?</p> <p>13 A. Yes, it was.</p> <p>14 Q. Is this something that doctors like</p> <p>15 yourself rely on in forming medical and scientific</p> <p>16 opinions?</p> <p>17 A. Yes, it is.</p> <p>18 Q. Did you read and review this in</p> <p>19 forming the opinions that you're giving here</p> <p>20 today?</p> <p>21 A. Yes, I did.</p> <p>22 Q. Is this a recognized and reliable</p> <p>23 publication for doctors in your field?</p> <p>24 A. Yes, it is.</p>

32 (Pages 122 to 125)

Vladimir Iakovlev, M.D.

Page 126	Page 128
<p>1 Q. What is -- can you publish that?</p> <p>2 What is the significance to you of Exhibit 22?</p> <p>3 A. So this is the authors, this is the</p> <p>4 journal. And if we can go to top part of the</p> <p>5 paper?</p> <p>6 Q. It says there "objectives". What</p> <p>7 does that objective word mean when it comes to a</p> <p>8 scientific journal like this?</p> <p>9 A. Objectives are the aims of the study</p> <p>10 or the goal. What they're trying to achieve or</p> <p>11 what they're trying to study.</p> <p>12 Q. Okay. What was the goal of what</p> <p>13 they were trying to achieve in this study?</p> <p>14 A. "In light of vaginal mesh safety</p> <p>15 concerns we reviewed our institutional</p> <p>16 experience with analytical process and</p> <p>17 pathologic findings of explanted</p> <p>18 vaginal meshes to identify problems and</p> <p>19 opportunities to facilitate improved</p> <p>20 documentation and research."</p> <p>21 Q. How many cases did they review?</p> <p>22 A. They reviewed 102 cases.</p> <p>23 Q. If you scroll down please to the</p> <p>24 conclusion section. Just briefly describe what</p>	<p>1 examination, sometimes it describes only one part</p> <p>2 of the findings, it does not list all pathological</p> <p>3 findings. And the information which is delivered</p> <p>4 cannot be related back to the clinical symptoms</p> <p>5 because it's incomplete.</p> <p>6 Q. And if we turn over to page 240 of</p> <p>7 this. And if you highlight the top part of the</p> <p>8 page. Why did you want to point this out to the</p> <p>9 jury, these highlights, Doctor?</p> <p>10 A. So these are images similar to what</p> <p>11 we saw. The images are of mesh. And you see</p> <p>12 those spaces you saw before in Ms. Ramirez's</p> <p>13 specimen. Those are clear spaces.</p> <p>14 Q. Okay.</p> <p>15 A. The same stain, H&amp;E stain. And they</p> <p>16 use the same technique. They use polarized light</p> <p>17 to identify where polypropylene is. And you can</p> <p>18 see these are polypropylene fibers here in the</p> <p>19 tissue.</p> <p>20 Q. And under -- the text underneath</p> <p>21 the -- under the figure for figure B it says,</p> <p>22 "Polarized micrograph showing brightly colored</p> <p>23 birefringent." Is that the word you used before</p> <p>24 in terms of what brightly means?</p>
Page 127	Page 129
<p>1 they concluded in this paper, Doctor?</p> <p>2 A. Their experience suggested that:</p> <p>3 "Gross and histologic examination</p> <p>4 is appropriate for mesh explants.</p> <p>5 Documentation of clinical history, mesh</p> <p>6 product and material was frequently</p> <p>7 incomplete and associated with</p> <p>8 increased submission of tissue for</p> <p>9 histologic examination and inaccurate</p> <p>10 gross impression of material type. We</p> <p>11 recommend..."</p> <p>12 That was their recommendation, "improved</p> <p>13 documentation to aid pathologic examination and</p> <p>14 enable future of pathophysiologic study of mesh</p> <p>15 complications."</p> <p>16 Q. Do you agree with that conclusion?</p> <p>17 A. I do. I frequently see --</p> <p>18 Q. And why do you agree with it? Why</p> <p>19 is it significant to you, Doctor?</p> <p>20 A. Because when I review the medical</p> <p>21 records I frequently see incomplete and partially</p> <p>22 inaccurate pathological diagnosis.</p> <p>23 Q. Please explain what you mean?</p> <p>24 A. Sometimes it's only gross</p>	<p>1 A. Yes. Bright means birefringent or</p> <p>2 birefringent means bright in polarized light.</p> <p>3 Q. You can take that down.</p> <p>4 Doctor, do you know if anyone else in</p> <p>5 your field of practice or in science has used the</p> <p>6 same methods to test if polypropylene degrades in</p> <p>7 the body?</p> <p>8 MR. HUTCHINSON: Objection.</p> <p>9 THE DEPONENT: Yes, I do.</p> <p>10 BY MR. ANDERSON:</p> <p>11 Q. And if we could see Exhibit 23?</p> <p>12 MR. HUTCHINSON: Ben, just for the</p> <p>13 record that was a foundation objection.</p> <p>14 BY MR. ANDERSON:</p> <p>15 Q. From your review of all of the</p> <p>16 records in this case, the internal documents that</p> <p>17 you reviewed in this case, any depositions that</p> <p>18 you reviewed, all of your work in the scientific</p> <p>19 area of explanted transvaginal meshes and hernia</p> <p>20 meshes, your analysis of over 300 explanted meshes</p> <p>21 and speaking at conferences and mingling with</p> <p>22 scientists around the world, are you aware of</p> <p>23 anyone that has used some of those similar methods</p> <p>24 to test if polypropylene degrades in the body,</p>



Vladimir Iakovlev, M.D.

Page 130	Page 132
<p>1 including polarized light in high magnification?</p> <p>2 MR. HUTCHINSON: Objection, compound</p> <p>3 question.</p> <p>4 THE DEPONENT: Yes, I am. I saw Ethicon</p> <p>5 scientists did the same -- used the same</p> <p>6 methodology.</p> <p>7 BY MR. ANDERSON:</p> <p>8 Q. Okay. So let's go to Exhibit 23.</p> <p>9 ---PLAINTIFF EXHIBIT NO. 23: Internal</p> <p>10 Ethicon Research Foundation document</p> <p>11 dated March 23, 1983. Bates labelled</p> <p>12 ETH.MESH.15955438 to ETH.MESH.15955439.</p> <p>13 BY MR. ANDERSON:</p> <p>14 Q. Is this something that you reviewed</p> <p>15 in your work in this case?</p> <p>16 A. Yes, I did.</p> <p>17 Q. Is IT something you relied on in</p> <p>18 forming your opinions in this case?</p> <p>19 A. Yes, I did.</p> <p>20 Q. Do you find it significant to your</p> <p>21 opinions in this case?</p> <p>22 A. Yes, I did.</p> <p>23 Q. If we could highlight the top. Can</p> <p>24 you just identify what this document is for the</p>	<p>1 from humans.</p> <p>2 Q. And what type of pathological</p> <p>3 technique were they using, Doctor?</p> <p>4 A. As you can see here they used light</p> <p>5 microscopy, exactly the same what I did, and</p> <p>6 polarized light to help identify the cracking.</p> <p>7 Q. And if you can just scroll to where</p> <p>8 we can see the center of this portion. Now, what</p> <p>9 were -- what preservation method did the</p> <p>10 pathologist use to preserve these Prolene</p> <p>11 specimens?</p> <p>12 A. The specimens were as normally</p> <p>13 preserved in formalin.</p> <p>14 Q. And then if we can just scroll down.</p> <p>15 Why did you want to highlight this last paragraph?</p> <p>16 A. They took photographs and they</p> <p>17 showed their findings in the photographs.</p> <p>18 Q. Okay.</p> <p>19 A. And apparently at that time the</p> <p>20 knowledge of Prolene or polypropylene cracking was</p> <p>21 so prevalent that Ethicon formed a committee, the</p> <p>22 committee was called "Prolene Microcrack</p> <p>23 Committee" to study the degradation of</p> <p>24 polypropylene.</p>
Page 131	Page 133
<p>1 record?</p> <p>2 A. So this is internal document from</p> <p>3 Ethicon Research Foundation dated March 23, 1983.</p> <p>4 Q. And if you look at the top paragraph</p> <p>5 what was the purpose of this study, Doctor? I'm</p> <p>6 sorry, you need -- the top part needs to go down</p> <p>7 all the way. Did you ask me to help you</p> <p>8 prehighlight some of this, Doctor?</p> <p>9 A. Yes, I did.</p> <p>10 Q. And what's the subject line of this</p> <p>11 study?</p> <p>12 A. Prolene, in brackets</p> <p>13 "polypropylene", Prolene is a brand name of</p> <p>14 Ethicon for polypropylene.</p> <p>15 Q. Is Prolene the type of polypropylene</p> <p>16 that is in the TVT-O?</p> <p>17 A. Yes, it is.</p> <p>18 Q. And the TVT-O that's in Ms. Ramirez?</p> <p>19 A. Body, yes it is.</p> <p>20 Q. Now let's go to that top paragraph.</p> <p>21 What were they doing in this internal Ethicon</p> <p>22 study regarding Prolene microcracks?</p> <p>23 A. They were studying specimens of</p> <p>24 Prolene sutures which were explanted or retrieved</p>	<p>1 Q. Okay. Let's go to next page of</p> <p>2 Exhibit 23. Let's highlight first the left side,</p> <p>3 top left side. Thank you.</p> <p>4 Why is this significant to your</p> <p>5 opinions, Doctor?</p> <p>6 A. So these are the images in</p> <p>7 transmitted light. You have to excuse me, this is</p> <p>8 a black and white copy.</p> <p>9 Q. I know they're not as pretty as the</p> <p>10 ones we saw before but just explain what you can</p> <p>11 see at least from the black and white copy?</p> <p>12 A. They show exactly the same slices of</p> <p>13 the mesh fibers, so they are cut like this.</p> <p>14 Exactly the same way as I did for Ms. Ramirez's</p> <p>15 specimen. And there is exactly the same bark.</p> <p>16 Q. Okay.</p> <p>17 A. Showing with the arrows.</p> <p>18 Q. Okay.</p> <p>19 A. And we can go to upper area here.</p> <p>20 Q. Okay.</p> <p>21 A. And it shows the bark around the</p> <p>22 fibers in regular transmitted light.</p> <p>23 Q. Now, on the right what do we have?</p> <p>24 Is that the same images?</p>

34 (Pages 130 to 133)

Vladimir Iakovlev, M.D.

Page 134	Page 136
<p>1 A. Then they use polarized light. The</p> <p>2 same polarized light as I use and they used it 30</p> <p>3 years ago. I was not aware of this document for a</p> <p>4 long time. I started my study, research of</p> <p>5 polypropylene degradation before I saw this</p> <p>6 document. And I was pleased to see that it was</p> <p>7 used 30 years ago. And these are the same fibers</p> <p>8 in polarized light. You can see how they are</p> <p>9 bright or birefringent.</p> <p>10 And then if we go to enlarge the area</p> <p>11 you can see some folding and some parts of the</p> <p>12 bark with cracks. This is the same bark.</p> <p>13 MR. HUTCHINSON: Move to strike as</p> <p>14 nonresponsive.</p> <p>15 BY MR. ANDERSON:</p> <p>16 Q. And, Doctor, did you review any</p> <p>17 other internal Ethicon documents where they</p> <p>18 studied these microcracks through this Prolene</p> <p>19 microcrack committee?</p> <p>20 A. Yes, I did.</p> <p>21 Q. Is this document significant to your</p> <p>22 opinions in this case?</p> <p>23 A. Yes, it is.</p> <p>24 Q. And did you review and rely upon</p>	<p>1 A. So again the same materials,</p> <p>2 polypropylene is explanted from human subjects.</p> <p>3 Q. And under the summary of that what</p> <p>4 were these explants preserved in before they were</p> <p>5 examined?</p> <p>6 A. So they were received to examine</p> <p>7 surface cracking and tensile strength.</p> <p>8 Q. What were they preserved in?</p> <p>9 A. They were preserved in formalin.</p> <p>10 Q. If we could go down do the next</p> <p>11 paragraph that you've asked to be highlighted.</p> <p>12 What's the significance of these highlighted</p> <p>13 sentences?</p> <p>14 A. So again they use the same methods,</p> <p>15 histological methods examining histological slides</p> <p>16 as I did for Ms. Ramirez, to examine them in</p> <p>17 regular light, or cross-sections of the specimens</p> <p>18 in regular light. And they used phloxine.</p> <p>19 Q. What's phloxine, Doctor?</p> <p>20 A. Phloxine is another histological</p> <p>21 dye.</p> <p>22 Q. Like the H&amp;E or the S100?</p> <p>23 A. Similar.</p> <p>24 Q. Okay.</p>
Page 135	Page 137
<p>1 them in informing your opinions?</p> <p>2 A. Yes, I did.</p> <p>3 Q. Can we please go to Exhibit 24? I'm</p> <p>4 showing you what has been marked as Exhibit 24.</p> <p>5 ---PLAINTIFF EXHIBIT NO. 24: Internal</p> <p>6 document from Ethicon Research</p> <p>7 Foundation dated May 2, 1984. Bates</p> <p>8 labelled ETH.MESH.15955462 to</p> <p>9 ETH.MESH.15955468.</p> <p>10 BY MR. ANDERSON:</p> <p>11 Q. And can you please identify that for</p> <p>12 the record?</p> <p>13 A. This is internal document from</p> <p>14 Ethicon Research Foundation.</p> <p>15 Q. Can you publish it and highlight the</p> <p>16 top part, including the top third of the document?</p> <p>17 Thank you.</p> <p>18 A. The document dates May 2nd, 1984.</p> <p>19 Q. So a year after the last document?</p> <p>20 A. Yes, it's about a year.</p> <p>21 Q. What's the subject here?</p> <p>22 A. Examination of Prolene polypropylene</p> <p>23 sutures from human cardiovascular explants.</p> <p>24 Q. Okay.</p>	<p>1 A. And they examined the specimens and</p> <p>2 they saw severe surface cracking. And the bark</p> <p>3 layer or the cracked layer was 3 to 4.5 microns.</p> <p>4 Q. Let me ask you about that level of 3</p> <p>5 to 4.5 microns. In your scientific research, and</p> <p>6 all of the explanted meshes that you've analyzed,</p> <p>7 is that the same or different in terms of 3 to 4.5</p> <p>8 micron depth of the bark cracking?</p> <p>9 A. It's the same. Well, they examine</p> <p>10 small number. I examine over 300 so my numbers</p> <p>11 are anywhere from 1 micron to 7 micron.</p> <p>12 Q. So hypothetically, I want you to</p> <p>13 assume with me there may be testimony in this case</p> <p>14 where someone might say that the depths of these</p> <p>15 cracks is so small it doesn't make any difference</p> <p>16 to the patient. Do you have an opinion about</p> <p>17 that?</p> <p>18 A. I do.</p> <p>19 Q. What's that opinion?</p> <p>20 A. Well, first of all it -- entire</p> <p>21 surface of the mesh is involved.</p> <p>22 Q. What do you mean by "involved"?</p> <p>23 A. Entire surface of the mesh is</p> <p>24 degraded, is brittle and it's cracked. And second</p>

35 (Pages 134 to 137)



Vladimir Iakovlev, M.D.

Page 138	Page 140
<p>1 point is that the size in pathology and in 2 medicine doesn't matter. For example, if we take 3 small structures like viruses they can be deadly, 4 like HIV virus or like Ebola virus. It's very 5 small but it can kill.</p> <p>6 Q. Okay. Let's turn over if we could 7 now to page 3 of this document. If we can 8 highlight from number 6 -- yes, please.</p> <p>9 Doctor, on page 3 of this document it 10 describes sample 6. And in the third -- in the 11 paragraph there in histological sections can you 12 please explain why this is significant to your 13 opinions?</p> <p>14 A. So again they describe a cracked 15 surface layer measuring 3 to 4.5 microns thick. 16 The layer was birefringent or bright, as we 17 discussed earlier. When examined under polarized 18 light microscopy, exactly the same phenomenon as 19 we saw before, it is bright in polarized light. 20 Phloxine stain had completely penetrated the 21 cracked layer. Again, a different dye stains it 22 purple again. Different molecules of the dye, 23 different electrostatic charge. It still dyes it, 24 it still stains it.</p>	<p>1 whether or not the longer the material was in the 2 body the more susceptible it was to cracking?</p> <p>3 A. There was some information about 4 cracks, they are more prevalent in older or longer 5 in vivo period.</p> <p>6 Q. Is that consistent with your 7 scientific research that you've done with regard 8 to degradation and the length of time that the 9 mesh was in the body?</p> <p>10 A. Yes, it is.</p> <p>11 Q. How so?</p> <p>12 A. The bark layer starts really thin. 13 Well, it starts with zero from day one and then it 14 grows slowly. Over the years it becomes thicker 15 and thicker and thicker, and thicker.</p> <p>16 Q. If we go down to the top page -- top 17 of the next page. At the top of page 4 of this 18 1984 study, plaintiff's Exhibit 24, why is that 19 significant to your opinions here, Doctor?</p> <p>20 A. So this is their conclusion. 21 "The cracked layer appeared blue in 22 gross specimens and blue dye particles 23 were evident in histological sections 24 of the layer. This would indicate that</p>
Page 139	Page 141
<p>1 Q. Okay. And the next part of that?</p> <p>2 A. And particles of blue dye, those 3 blue granules were evident within the cracked 4 layer. So they saw exactly the same 30 years ago. 5 Those blue granules were in the bark in 1984.</p> <p>6 Q. And just to be clear, in both the 7 1983 internal Ethicon Prolene crack study, and the 8 1984 Ethicon internal Prolene crack study not all 9 of those fibers were cracked, correct?</p> <p>10 MR. HUTCHINSON: Objection, leading. 11 BY MR. ANDERSON:</p> <p>12 Q. Were all of those fibers cracked?</p> <p>13 A. No, not all of them were cracked.</p> <p>14 Q. Just to be clear, Doctor, in both 15 the Ethicon 1983 Microcrack Committee study, and 16 the Ethicon 1984 Ethicon Microcrack Committee 17 study were all of those fibers cracked or 18 degraded?</p> <p>19 A. Well, the report was that some of 20 them were not cracked or at least they did not see 21 cracking.</p> <p>22 Q. Okay. And did these reports did 23 they determine whether or not the cracking was 24 time dependent? In other words, did they report</p>	<p>1 the layer is dyed Prolene polymer and 2 not an isolated protein coating on the 3 strands."</p> <p>4 Q. Why is that significant to you, 5 Doctor?</p> <p>6 A. These were exactly the same 7 conclusions as I independently arrived 30 years 8 after. Thirty years ago Ethicon scientists used 9 the same methods and they concluded that the 10 cracked layer is degraded polypropylene and not a 11 protein layer, not a biofilm.</p> <p>12 Q. If we could go to page 6 of this 13 report? I want to highlight that top part. 14 Is this significant to your report here, 15 Doctor, the description of certain wet and dry 16 conditions?</p> <p>17 A. Yes, it is.</p> <p>18 Q. Can you please explain?</p> <p>19 A. So when the surface of the cracked 20 fibers is dry it's much easier to see the cracks. 21 They are more dramatic in dry sample. When the 22 surface was wet it's not as easy to see the 23 cracks. So sometimes --</p> <p>24 Q. Why is that?</p>

36 (Pages 138 to 141)

Vladimir Iakovlev, M.D.

Page 142	Page 144
<p>1 A. Water just fills the cracks and you</p> <p>2 don't see them.</p> <p>3 Q. And if we turn to page 7 please.</p> <p>4 What are we seeing in that upper image, Doctor?</p> <p>5 A. This is a similar image we saw</p> <p>6 before the polypropylene fiber is sectioned in</p> <p>7 histological section and examined in polarized</p> <p>8 light. And this part is the nondegraded core of</p> <p>9 the fiber. And this layer, as you can see a</p> <p>10 scaling layer, is degraded bark.</p> <p>11 Q. And it says "birefringent", is that</p> <p>12 that word that means brightly again?</p> <p>13 A. Brightly, bright again. It's</p> <p>14 phloxine staining, bright in polarized light,</p> <p>15 degraded layer of polypropylene or Prolene.</p> <p>16 Q. What are we seeing in the image just</p> <p>17 below that if we could, Doctor?</p> <p>18 A. And this is again a cross-section of</p> <p>19 a fiber like this tree slab.</p> <p>20 Q. Okay.</p> <p>21 A. Cross-section. And we just see</p> <p>22 quarter of it. And we see bark layer or</p> <p>23 degradation layer on the outer surface. So in</p> <p>24 this image it's in regular light, this part is the</p>	<p>1 A. This is a comparison of the Ethicon</p> <p>2 study and the images I took from Ms. Ramirez's</p> <p>3 specimen. The first combination of images shows</p> <p>4 microphotographs taken 30 years ago by Ethicon</p> <p>5 scientists studying Prolene sutures explanted from</p> <p>6 people. And this image, or the image on lower</p> <p>7 right shows Ms. Ramirez's specimen in polarized</p> <p>8 light. And you can see the similarity. Bright</p> <p>9 core, bright bark and then dark surrounding</p> <p>10 tissue, dark surrounding tissue here.</p> <p>11 Q. What do we see in the lower right</p> <p>12 image, if you can blow that up please for me.</p> <p>13 A. This is comparison of mesh fibers</p> <p>14 examined in regular light. And you can see the</p> <p>15 similarity. Mesh fiber with cracked outer bark or</p> <p>16 cracked outer layer here in Ms. Ramirez's specimen</p> <p>17 examined in 2015. And this is a mesh or Prolene</p> <p>18 suture examined in 1984. And we can see the</p> <p>19 similarity.</p> <p>20 So this was drawn by Ethicon scientist</p> <p>21 in 1984. This is the bark layer with the cracks.</p> <p>22 And this is 2015, 30 years after that. These are</p> <p>23 blue granules in the bark layer. This is Prolene,</p> <p>24 it's not protein.</p>
Page 143	Page 145
<p>1 core and this is degraded layer. And they use the</p> <p>2 same arrows. I used the same arrows or similar</p> <p>3 arrows 30 years after that.</p> <p>4 Q. With my help did you prepare a slide</p> <p>5 comparing the findings from these Ethicon</p> <p>6 scientist and your findings from Ms. Ramirez's</p> <p>7 explanted mesh?</p> <p>8 A. Yes, I did.</p> <p>9 Q. Do you think it would be helpful in</p> <p>10 informing the jury or your opinions?</p> <p>11 A. Yes, it will.</p> <p>12 Q. Is it significant to your opinions</p> <p>13 here?</p> <p>14 A. Yes, it is.</p> <p>15 Q. Okay. Let's pull up Exhibit 25</p> <p>16 please. I'm showing you what's been premarked as</p> <p>17 plaintiff's Exhibit 25 for demonstrative purposes</p> <p>18 only.</p> <p>19 ---PLAINTIFF EXHIBIT NO. 25: Two pages</p> <p>20 depicting high magnification images for</p> <p>21 comparison.</p> <p>22 BY MR. ANDERSON:</p> <p>23 Q. Please explain what we're seeing</p> <p>24 here, Doctor?</p>	<p>1 Q. Demonstrating what to you,</p> <p>2 Dr. Iakovlev?</p> <p>3 A. It demonstrates that Ethicon</p> <p>4 scientists knew that Prolene degrades in the body</p> <p>5 in 1984, and they determined that using exactly</p> <p>6 the same methodology that I used to examine</p> <p>7 Ms. Ramirez's specimen and determine that TVT-O</p> <p>8 degraded while in the body of Ms. Ramirez.</p> <p>9 Q. Thank you, you can take that down.</p> <p>10 Doctor, as part of your evaluation in</p> <p>11 this case did you rule out any other causes of the</p> <p>12 scarring the foreign body type inflammation and</p> <p>13 the nerve involvement in Ms. Ramirez's slide?</p> <p>14 A. Yes, I did.</p> <p>15 Q. What did you do to rule out all</p> <p>16 other causes for these tissue changes as it</p> <p>17 related to the TVT-O mesh in Ms. Ramirez?</p> <p>18 A. I examined the specimen grossly, I</p> <p>19 examined it microscopically and I saw no natural</p> <p>20 disease like cancer. All pathological cases were</p> <p>21 related to the mesh. My findings were exactly the</p> <p>22 same in this respect as the findings of initial</p> <p>23 pathologist.</p> <p>24 Q. Doctor, based upon your background,</p>

37 (Pages 142 to 145)

Vladimir Iakovlev, M.D.

Page 146	Page 148
<p>1 training and experience, your review of over 300  2 explanted meshes, your review of the medical  3 records of hundreds of explanted mesh patients,  4 your scientific publications, your review of the  5 literature and your review of Ms. Ramirez's  6 medical records, do you have an opinion, to a  7 reasonable degree of medical certainty, as to the  8 cause of Ms. Ramirez's pelvic pain?  9 A. Yes I do.  10 Q. And what is that opinion?  11 A. My opinion is --  12 MR. HUTCHINSON: Objection, foundation.  13 BY MR. ANDERSON:  14 Q. Go ahead?  15 A. As I said, there was no natural  16 disease, there was no other foreign body. All  17 pathology in the excised specimens, and the  18 specimens which were excised to treat the  19 complications was related to the mesh. And those  20 were bridging fibrosis, scar encapsulation, scar  21 plating, foreign body type inflammation, nerve  22 entrapment, and all of these changes caused  23 complications in Ms. Ramirez.  24 Q. And was that complication including</p>	<p>1 MR. HUTCHINSON: Same objection,  2 foundation.  3 BY MR. ANDERSON:  4 Q. Go ahead  5 A. The mesh triggered tissue reaction.  6 The mesh degraded itself, it triggered bridging  7 fibrosis, scar encapsulation, scar plating,  8 foreign body type inflammation, nerve entrapment,  9 and all of these changes caused this complication.  10 Q. Do you have an opinion, to a  11 reasonable degree of medical certainty, based upon  12 your background, training, experience, your review  13 of over 300 explanted polypropylene meshes, your  14 publications in the field, your presentations at  15 conferences around the world, including invited  16 presentations to mesh manufacturers, your review  17 of the records in this case, and your review of  18 the explants, and all of your microscopic  19 analysis, do you have an opinion as to whether or  20 not the pathological analysis you've done has  21 shown that Ms. Ramirez's urinary symptoms were due  22 to TVT-O?  23 MR. HUTCHINSON: Objection, foundation.  24 THE DEPONENT: Yes, I do.</p>
Page 147	Page 149
<p>1 pelvic pain?  2 MR. HUTCHINSON: Objection, foundation.  3 THE DEPONENT: Yes.  4 BY MR. ANDERSON:  5 Q. And based upon all of your  6 background, training, experience, your scientific  7 work, your review of the medical records in this  8 case, do you have an opinion -- and you review of  9 thousands of other pages of medical records for  10 the hundreds of explants that you say you examined  11 as part of your work and your research, do you  12 have an opinion as to whether or not the TVT-O  13 mesh caused pain with sexual intercourse for  14 Ms. Ramirez?  15 MR. HUTCHINSON: Objection, foundation.  16 THE DEPONENT: Yes, I do.  17 BY MR. ANDERSON:  18 Q. What is that opinion?  19 A. My opinion is that the mesh and in  20 the mesh related changes in the tissue caused pain  21 with sexual intercourse for Ms. Ramirez.  22 Q. And do you have an opinion as to how  23 it caused pain for sexual intercourse?  24 A. Yes, I do.</p>	<p>1 BY MR. ANDERSON:  2 Q. What is that opinion?  3 A. My opinion is that the sling and  4 sling-related tissue changes caused scarring, scar  5 contraction, tightening of the mesh and urinary  6 symptoms. As to how this tightening of the mesh  7 manifested in terms of urinary symptoms I would  8 defer this to urogynecologist.  9 Q. Doctor, with your help did you help  10 me prepare a slide for your clinico-pathological  11 findings as they relate to your opinion in  12 Ms. Ramirez's case?  13 A. I did.  14 Q. And for demonstrative purposes only  15 can you please pull up the slide? Doctor, can you  16 please explain the slide that you prepared here  17 for the jury regarding your summary of  18 pathological findings and your  19 clinico-pathological correlation?  20 A. So the main pathological abnormality  21 in the excised tissue, in the tissue which was  22 excised to treat the complications, was presence  23 of foreign body and that foreign body was the  24 mesh. There was no other foreign body.</p>

38 (Pages 146 to 149)

Vladimir Iakovlev, M.D.

Page 150	Page 152
<p>1 Now, examining further the sling was</p> <p>2 found curled or roped, which was correlating with</p> <p>3 the clinical description of bow stringing. Making</p> <p>4 a tight rope like a bow string. This was caused</p> <p>5 by scarring and contraction within the curled</p> <p>6 mesh.</p> <p>7 Q. Okay. Next bullet point.</p> <p>8 A. There was entrapment of nerves in</p> <p>9 the scar and in the mesh which was correlated with</p> <p>10 the pain.</p> <p>11 Q. And the next bullet point?</p> <p>12 A. There was also foreign body type</p> <p>13 inflammation which was correlating with further</p> <p>14 scarring and pain. The mesh itself was found to</p> <p>15 be degraded. It was failing on its own.</p> <p>16 Q. And your last bullet point, why is</p> <p>17 that significant?</p> <p>18 A. As important in pathology for all</p> <p>19 specimens we examine, there was no natural</p> <p>20 disease. There is no malignancy or nonmalignant</p> <p>21 disease in the tissue. All changes were triggered</p> <p>22 by the mesh.</p> <p>23 Q. Doctor, do you have an opinion, to a</p> <p>24 reasonable degree of medical certainty, based upon</p>	<p>1 A. I do.</p> <p>2 Q. And what is that opinion?</p> <p>3 MR. HUTCHINSON: Same objection,</p> <p>4 foundation.</p> <p>5 BY MR. ANDERSON:</p> <p>6 Q. What is that opinion?</p> <p>7 A. My opinion is that the remaining</p> <p>8 parts of the TVT-O sling which still remain in</p> <p>9 Ms. Ramirez's body will continue to cause all of</p> <p>10 those changes, pathological changes I described</p> <p>11 before, and will pose risk for pain for</p> <p>12 Ms. Ramirez.</p> <p>13 Q. For how long?</p> <p>14 A. As long as mesh stays there. And</p> <p>15 because there is still damaged tissue, scarring</p> <p>16 left after the mesh in the area where it was</p> <p>17 excised, and scarring left after the mesh</p> <p>18 surgeries, that scar tissue also poses risk for</p> <p>19 clinical complications.</p> <p>20 MR. HUTCHINSON: Move to strike as</p> <p>21 nonresponsive.</p> <p>22 BY MR. ANDERSON:</p> <p>23 Q. Thank you, Doctor, no further</p> <p>24 questions.</p>
Page 151	Page 153
<p>1 your knowledge, training, experience, work as a</p> <p>2 pathologist for over 15 years, your work on this</p> <p>3 case reviewing the medical records of Ms. Ramirez,</p> <p>4 all of the work that you've done in the field that</p> <p>5 we've previously described, as to whether or not</p> <p>6 these pathological changes in the tissue of</p> <p>7 Ms. Ramirez, that you've just described, are</p> <p>8 related to her clinical symptoms of chronic</p> <p>9 vaginal pelvic pain, pain with intercourse and</p> <p>10 urinary symptoms?</p> <p>11 MR. HUTCHINSON: Objection, foundation.</p> <p>12 THE DEPONENT: I do.</p> <p>13 BY MR. ANDERSON:</p> <p>14 Q. What is that opinion?</p> <p>15 A. My opinion is that the mesh and</p> <p>16 mesh-related changes in the tissue caused chronic</p> <p>17 pelvic vaginal pain, pain with intercourse and</p> <p>18 urinary symptoms for Mr. Ramirez.</p> <p>19 Q. And do you have an opinion, based</p> <p>20 upon your background, training, experience, and</p> <p>21 all of your work in this case, as to whether or</p> <p>22 not the pieces of mesh that are still in</p> <p>23 Ms. Ramirez's body will continue to present a risk</p> <p>24 for other complications and changes in her tissue?</p>	<p>1 A. Thank you.</p> <p>2 THE VIDEOGRAPHER: Going off the record.</p> <p>3 The time is 11:58 a.m.</p> <p>4 --- Lunch break taken</p> <p>5 THE VIDEOGRAPHER: Back on the record at</p> <p>6 1:09 p.m.</p> <p>7 CROSS-EXAMINATION BY MR. HUTCHINSON:</p> <p>8 Q. Good afternoon, Dr. Iakovlev.</p> <p>9 A. Good afternoon.</p> <p>10 Q. My name is Chad Hutchinson and I</p> <p>11 represent Ethicon and Johnson &amp; Johnson in this</p> <p>12 case and I'm going to need to ask you some</p> <p>13 questions, okay?</p> <p>14 A. Okay.</p> <p>15 Q. You're a pathologist who works in</p> <p>16 Canada, is that right?</p> <p>17 A. That's correct.</p> <p>18 Q. And I believe you told us earlier</p> <p>19 this morning that you grew up in Russia?</p> <p>20 A. That's correct.</p> <p>21 Q. And you served in the Russian</p> <p>22 military?</p> <p>23 MR. ANDERSON: Objection.</p> <p>24 THE DEPONENT: Yes, I did.</p>

39 (Pages 150 to 153)

Vladimir Iakovlev, M.D.

Page 154	Page 156
<p>1 BY MR. HUTCHINSON:</p> <p>2 Q. And we're in Canada right now, is</p> <p>3 that right?</p> <p>4 A. That's correct.</p> <p>5 Q. Now, Dr. Iakovlev, the jury who is</p> <p>6 watching this video is from Texas. You've never</p> <p>7 practiced medicine in Texas have you?</p> <p>8 A. No.</p> <p>9 Q. You've never been to Texas?</p> <p>10 A. Just in the airport.</p> <p>11 Q. And, Doctor, you've been licensed to</p> <p>12 practiced medicine in the State of Texas have you?</p> <p>13 A. Not in the state of Texas.</p> <p>14 Q. In fact, Doctor, let's be more</p> <p>15 specific, you've never practiced medicine anywhere</p> <p>16 in the United States have you?</p> <p>17 A. That's correct.</p> <p>18 Q. And you applied for a residency</p> <p>19 program in the USA didn't you?</p> <p>20 A. I applied to both, to Canada and</p> <p>21 residency at the same time.</p> <p>22 Q. That's correct. And you didn't get</p> <p>23 in the USA did you?</p> <p>24 A. That's not correct. I got into</p>	<p>1 A. That's correct.</p> <p>2 Q. And that's another company that</p> <p>3 makes mesh?</p> <p>4 A. That's correct.</p> <p>5 Q. And you've testified against Boston</p> <p>6 Scientific haven't you?</p> <p>7 A. I did.</p> <p>8 Q. Another company that makes mesh?</p> <p>9 A. That's correct.</p> <p>10 Q. And now you're giving testimony</p> <p>11 against Ethicon, is that right?</p> <p>12 A. That's correct.</p> <p>13 Q. In fact you've always testified for</p> <p>14 the plaintiffs against any manufacturer of mesh</p> <p>15 products, is that correct, sir.</p> <p>16 A. I always testified for the patients.</p> <p>17 I think it's natural for a doctor.</p> <p>18 Q. And, Doctor, you charge \$475 an hour</p> <p>19 for your time, is that correct?</p> <p>20 A. That's correct.</p> <p>21 Q. How many years have you been doing</p> <p>22 this, Dr. Iakovlev?</p> <p>23 MR. ANDERSON: Objection to form.</p> <p>24 THE DEPONENT: Um, I became involved --</p>
Page 155	Page 157
<p>1 pathology residency in Canada, because when the</p> <p>2 match happens you can get only one spot.</p> <p>3 Q. But you applied for a residency</p> <p>4 program in the United States, is that correct?</p> <p>5 A. That's correct.</p> <p>6 MR. ANDERSON: Just show my objection to</p> <p>7 this entire line of questions.</p> <p>8 BY MR. HUTCHINSON:</p> <p>9 Q. And you never participated in the</p> <p>10 residency program in the United States, correct?</p> <p>11 MR. ANDERSON: Objection.</p> <p>12 THE DEPONENT: That's correct.</p> <p>13 BY MR. HUTCHINSON:</p> <p>14 Q. And, Dr. Iakovlev, I want to talk</p> <p>15 about your history as an expert witness in the</p> <p>16 mesh litigation. You've testified for the</p> <p>17 plaintiffs against American Medical Systems, AMS,</p> <p>18 is that right?</p> <p>19 A. That's correct.</p> <p>20 Q. And that's one company that makes</p> <p>21 mesh?</p> <p>22 A. That's correct.</p> <p>23 Q. And you've testified for the</p> <p>24 plaintiffs against Bard, is that correct?</p>	<p>1 first I became involved in the mesh research in</p> <p>2 2012. And then I became in mesh litigation,</p> <p>3 without knowing this there is litigation. I was</p> <p>4 just called to examine something for litigation in</p> <p>5 2013.</p> <p>6 BY MR. HUTCHINSON:</p> <p>7 Q. So, Dr. Iakovlev, let me ask you</p> <p>8 this. Since 2013 why don't you tell the jury how</p> <p>9 much money in U.S. currency that you've made in</p> <p>10 total from all the mesh work that you've done?</p> <p>11 A. Um, I don't know for the 2015. Last</p> <p>12 time --</p> <p>13 Q. I'm sorry, move to strike as</p> <p>14 nonresponsive. Dr. Iakovlev --</p> <p>15 MR. ANDERSON: He's trying to give you a</p> <p>16 summary and break it down.</p> <p>17 MR. HUTCHINSON: I understand that.</p> <p>18 BY MR. HUTCHINSON:</p> <p>19 Q. But I need you to give me in total</p> <p>20 how much money that you've made in U.S. currency</p> <p>21 giving testimony against mesh manufacturers since</p> <p>22 2013?</p> <p>23 MR. ANDERSON: Objection.</p> <p>24 MR. FREESE: Hold on a sec. Dr.</p>

40 (Pages 154 to 157)



Vladimir Iakovlev, M.D.

Page 158	Page 160
<p>1 Iakovlev, you can answer the question. We're not 2 going to have the interruptions. You ask the 3 question, if you don't think it's responsive you 4 move to strike but we're not going to do this, 5 Chad. 6 MR. HUTCHINSON: That's exactly what I 7 did and he didn't answer the question. 8 MR. FREESE: No, you interrupted him. 9 MR. HUTCHINSON: No, I didn't. 10 MR. FREESE: Yes, you did. You 11 interrupted him. So you're going to ask the 12 question, the doctor is going to answer and then 13 you're either going to move on to another question 14 or you're going to move to strike as 15 nonresponsive. But you're not going to interrupt 16 the witness and he's not going to interrupt you. 17 MR. HUTCHINSON: I didn't interrupt the 18 witness. 19 MR. FREESE: Yes, you did. You 20 absolutely did. 21 BY MR. HUTCHINSON: 22 Q. Dr. Iakovlev, you can answer the 23 question. 24 A. I can only tell you up to 2014</p>	<p>1 And he says he doesn't know for '15. What part of 2 that didn't you understand? 3 BY MR. HUTCHINSON: 4 Q. Dr. Iakovlev, you can answer the 5 question? 6 MR. ANDERSON: Answer the question. 7 THE DEPONENT: I will just repeat it 8 again. I cannot give you total number. I can 9 give you total number up to the year I completed 10 my taxes. 11 BY MR. HUTCHINSON: 12 Q. And what year did you complete your 13 taxes? 14 A. 2014. 15 Q. And what is that amount up until 16 2014? 17 A. 170,000. 18 Q. Doctor, from 2014 until now, April 19 2016, you've made over a million dollars in U.S. 20 currency haven't you? 21 A. I don't think so. I don't know. 22 Q. You can't answer that question? 23 A. I can't answer that question. 24 Q. For the Ramirez case, Dr. Iakovlev,</p>
Page 159	Page 161
<p>1 because I've done taxes only for 2014. I haven't 2 done taxes for 2015 yet. 3 Q. Move to strike as nonresponsive. 4 Dr. Iakovlev, my question is since 2013 5 tell the jury how much money that you've made in 6 U.S. currency in total in all the mesh litigation 7 that you've been involved in. 8 MR. ANDERSON: Objection. Go ahead. 9 THE DEPONENT: That was my answer. I 10 can give you number only up to 2014. 11 BY MR. HUTCHINSON: 12 Q. You can't give us a number before 13 2014? Is that what you said? 14 A. I just became involved at the end of 15 2013. I didn't make -- I don't think I made much 16 or anything in 2013. 17 Q. But my question, Doctor -- move to 18 strike as nonresponsive. My question is, I want 19 to know in total how much money that you've 20 received in U.S. currency from being an expert in 21 the mesh litigation since 2013? 22 MR. ANDERSON: Objection. That's what 23 he's trying to tell you. He said he can tell you 24 only up to 2014 and you keep saying "in total".</p>	<p>1 how much time have you spent on the Ramirez case? 2 A. Um, you have my billing. It 3 describes everything. 4 Q. Move to strike as nonresponsive. 5 Dr. Iakovlev, how much time have you 6 spent on the Ramirez case? 7 A. I don't remember exact number of 8 hours. I mean, usually it takes about 20 hours 9 for me to make one expert report. 10 Q. Dr. Iakovlev, this morning you told 11 us that you were an anatomical pathologist, is 12 that correct? 13 A. That's correct. 14 Q. You're not a clinical pathologist 15 are you? 16 A. I'm not. 17 Q. You're not a biochemical pathologist 18 are you? 19 A. Well, clinical pathologist and 20 biochemical pathologist are the same thing. Usual 21 term for United States and Canada is clinical 22 pathologist or general pathologist. 23 Q. But you're not a biochemical 24 pathologist are you, Doctor?</p>

41 (Pages 158 to 161)

Vladimir Iakovlev, M.D.

Page 162	Page 164
<p>1 A. As I said, we don't use that term, 2 biochemical pathologist. 3 Q. Doctor -- 4 A. The correct term the clinical 5 pathologist and I'm not clinical pathologist. 6 Q. Who doesn't use the term 7 "biochemical pathologist"? 8 A. Pathologists. 9 Q. Okay. Doctor, I want to hand you 10 your deposition from the Jennifer Ramirez case. 11 You testified under oath, didn't you, in the 12 Jennifer Ramirez case, the case that we're here 13 about today? 14 A. That's correct. 15 Q. And, Doctor, if you'll turn to page 16 102, line 17. Page 102, line 17. Are you there 17 with me? 18 A. Yes, I am. 19 Q. It says, "I don't know. I'm not a 20 treating physician and I'm not a biochemical 21 pathologist." Did I read that correctly, sir? 22 A. You do. 23 Q. Those are your own words aren't 24 they?</p>	<p>1 the accuracy of that deposition didn't you, sir? 2 MR. ANDERSON: Objection. 3 THE DEPONENT: Sometimes I do, sometimes 4 I don't. Sometimes I don't review the 5 transcripts. 6 BY MR. HUTCHINSON: 7 Q. Doctor, you're not a microbiologist 8 either are you? 9 A. That's correct. 10 Q. And you're not a urologist? 11 A. I'm not. 12 Q. And you're not a urogynecologist? 13 A. I'm not. 14 Q. Those are specialties outside of 15 your field. Is that correct, sir? 16 A. That's correct. 17 Q. And you don't treat or counsel 18 patients who have urinary symptoms like 19 Ms. Ramirez do you? 20 A. I don't. 21 Q. And you don't counsel or treat 22 patients who have dyspareunia do you? 23 A. I don't. 24 Q. And you don't prescribe medicine for</p>
Page 163	Page 165
<p>1 A. I don't know. That's what 2 transcript said. I don't know if I said that 3 because it's not our usual term. It says clinical 4 pathologist. 5 Q. Dr. Iakovlev, are you telling the 6 jury that the transcript for the Jennifer Ramirez 7 case is wrong? 8 A. Could be because it's not our usual 9 term. 10 Q. Do you have any evidence, 11 Dr. Iakovlev, that Ms. Ramirez's transcript is 12 wrong? 13 MR. ANDERSON: Objection. Go ahead. 14 THE DEPONENT: No, I'm just that this is 15 not an accepted term. The subspecialties in 16 pathology are anatomical pathology and clinical 17 pathology. 18 BY MR. HUTCHINSON: 19 Q. And Dr. Iakovlev, did you sign the 20 errata sheet for your deposition? 21 A. For this transcript? 22 Q. Yes, sir. 23 A. I don't know. 24 Q. You had the opportunity to review</p>	<p>1 pelvic pain do you, Dr. Iakovlev? 2 A. I don't. 3 Q. And you don't implant mesh do you, 4 sir? 5 A. I don't. 6 Q. And you don't explant mesh do you, 7 sir? 8 A. I don't. 9 Q. I want to talk specifically about 10 Ms. Ramirez for a minute. Okay? 11 A. Okay. 12 Q. Now, you know she received a TVT-O 13 product in September of 2010, is that right? 14 A. That's correct. 15 Q. And you don't know whether her 16 incontinence was cured or fixed by the TVT-O do 17 you? 18 A. Well, that's not what purpose of my 19 expert opinion. I'm not here to testify on the 20 efficacy of the device. 21 Q. Move to strike as nonresponsive. 22 Doctor, my question is you don't know 23 whether Ms. Ramirez's incontinence was corrected 24 by the TVT-O do you, sir?</p>

42 (Pages 162 to 165)

Vladimir Iakovlev, M.D.

Page 166	Page 168
<p>1 A. I don't.</p> <p>2 Q. And you haven't examined Ms. Ramirez</p> <p>3 have you?</p> <p>4 A. No, I have not.</p> <p>5 Q. You haven't read her deposition have</p> <p>6 you?</p> <p>7 A. I have not.</p> <p>8 Q. You haven't talked with her have</p> <p>9 you?</p> <p>10 A. I have not.</p> <p>11 Q. And you haven't talked with any of</p> <p>12 Ms. Ramirez's treating doctors have you?</p> <p>13 A. That's correct.</p> <p>14 Q. So as I understand it you're basing</p> <p>15 your opinions on the medical records and your</p> <p>16 examination of the explant, is that right?</p> <p>17 A. That's correct.</p> <p>18 Q. Let's talk about the medical records</p> <p>19 for just a minute. You asked for all of her</p> <p>20 medical records didn't you?</p> <p>21 A. Yes, I did.</p> <p>22 Q. And then you wrote a report?</p> <p>23 A. Well, I examined the specimen as</p> <p>24 well after I went through the records.</p>	<p>1 dyspareunia before September of 2010 does it, sir?</p> <p>2 A. No, it doesn't.</p> <p>3 Q. And you can't tell us what you did</p> <p>4 to rule out any pre-existing dyspareunia can you,</p> <p>5 sir?</p> <p>6 A. Yes, I can.</p> <p>7 Q. Dr. Iakovlev, I want you to look at</p> <p>8 your deposition again.</p> <p>9 A. Yes.</p> <p>10 Q. Page 96, line 5.</p> <p>11 A. I do.</p> <p>12 Q. And it says, "As we sit here right</p> <p>13 now", and by the way, Dr. Iakovlev, you understand</p> <p>14 you're under oath right now don't you?</p> <p>15 A. I do.</p> <p>16 Q. And you understand you were under</p> <p>17 oath at the time you gave testimony in</p> <p>18 Ms. Ramirez's case didn't you?</p> <p>19 A. I do.</p> <p>20 Q. And it says, "As we sit here now you</p> <p>21 can't tell me what you do to rule out her</p> <p>22 pre-existing dyspareunia?" And your answer is,</p> <p>23 "That's not my job." Did I read that correctly?</p> <p>24 MR. ANDERSON: No. Objection. You have</p>
Page 167	Page 169
<p>1 Q. Doctor, I want to hand you the</p> <p>2 report that you've done for Jennifer Ramirez and</p> <p>3 we'll mark it as defendant's Exhibit 1.</p> <p>4 ---DEFENSE EXHIBIT NO. 1: Expert</p> <p>5 report of Dr. Vladimir Iakovlev re.</p> <p>6 Jennifer Ramirez, dated April 24, 2015.</p> <p>7 BY MR. HUTCHINSON:</p> <p>8 Q. That's a copy of your report that</p> <p>9 you did for Jennifer Ramirez isn't it, sir?</p> <p>10 A. Yes, it is.</p> <p>11 Q. And your report includes a summary</p> <p>12 of clinical records, is that right?</p> <p>13 A. Yes.</p> <p>14 Q. And your summary doesn't say</p> <p>15 anything about Ramirez -- Ms. Ramirez having</p> <p>16 dyspareunia before September of 2010, does it?</p> <p>17 A. Just give me a second and I'll go to</p> <p>18 the summary.</p> <p>19 Q. Doctor, I'm going to help you out,</p> <p>20 it's on the first page of your case-specific</p> <p>21 report.</p> <p>22 A. I found it. This is my summary.</p> <p>23 Q. That's correct. And your summary</p> <p>24 doesn't say anything about Ms. Ramirez having</p>	<p>1 to read the entire answer.</p> <p>2 MR. HUTCHINSON: I'm not finished yet</p> <p>3 MR. ANDERSON: You said, "Did I read</p> <p>4 that correctly?"</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. Are you following me, Dr. Iakovlev?</p> <p>7 A. I'm following you but I have to read</p> <p>8 the whole sequence of questions before I answer</p> <p>9 you.</p> <p>10 Q. Fine. Dr. Iakovlev, are you</p> <p>11 finished?</p> <p>12 A. Not yet.</p> <p>13 Q. Are you finished Dr. Iakovlev?</p> <p>14 A. Yes, I'm finished.</p> <p>15 Q. Dr. Iakovlev, that wasn't your job</p> <p>16 to rule out pre-existing dyspareunia was it?</p> <p>17 A. Okay. Let me read the entire</p> <p>18 paragraph. I would have to look --</p> <p>19 Q. Excuse me, I'm going to move to</p> <p>20 strike as nonresponsive.</p> <p>21 MR. FREESE: You're doing what I just</p> <p>22 asked you not to do.</p> <p>23 MR. ANDERSON: You cannot interrupt him.</p> <p>24 MR. HUTCHINSON: No, I'm not.</p>

43 (Pages 166 to 169)

Vladimir Iakovlev, M.D.

Page 170	Page 172
<p>1 MR. FREESE: He's speaking.</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. My question is very simple.</p> <p>4 MR. FREESE: We're going to --</p> <p>5 MR. HUTCHINSON: My question is if he</p> <p>6 was finished or not.</p> <p>7 MR. FREESE: Chad, we're going to be</p> <p>8 civil with each other and we're going to go by the</p> <p>9 rules. He was speaking and you interrupted him.</p> <p>10 He is going to answer the question the best way he</p> <p>11 can. You then can move to strike or not. Go</p> <p>12 ahead, Doctor. If you want to withdraw the</p> <p>13 question and ask it again and let him answer</p> <p>14 that's fine.</p> <p>15 BY MR. HUTCHINSON:</p> <p>16 Q. My question is, Dr. Iakovlev, are</p> <p>17 you finished reading your deposition testimony?</p> <p>18 A. Those two pages?</p> <p>19 Q. Yes. Are you finished reading them?</p> <p>20 A. Yes, I finished.</p> <p>21 Q. Dr. Iakovlev, it wasn't your job to</p> <p>22 rule out pre-existing dyspareunia was it?</p> <p>23 A. So I will read you my answer that I</p> <p>24 gave at the deposition.</p>	<p>1 Q. And you don't know whether</p> <p>2 Ms. Ramirez had any type of pelvic pain before</p> <p>3 2010 do you?</p> <p>4 A. I do. She had some pelvic pain</p> <p>5 related to her benign tumors in the uterus, and</p> <p>6 she had pain from menstrual periods.</p> <p>7 Q. And -- I'm sorry. Were you</p> <p>8 finished?</p> <p>9 A. That's why the uterus was removed.</p> <p>10 Q. Doctor, I want to hand you what</p> <p>11 we'll mark as defense Exhibit 2 to your</p> <p>12 deposition.</p> <p>13 ---DEFENSE EXHIBIT NO. 2: Medical</p> <p>14 report from Baptist Health System re.</p> <p>15 Jennifer Galindo dated 1/21/2015.</p> <p>16 Bates labelled RAMIREZJ_BAHSY_MDR00564.</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. You've seen this record before</p> <p>19 haven't you, sir?</p> <p>20 A. Yes, I have.</p> <p>21 Q. And if we look at the middle where</p> <p>22 it says, "Chief complaint, very heavy menstrual</p> <p>23 periods. Pelvic pain." Did I read that</p> <p>24 correctly, sir?</p>
Page 171	Page 173
<p>1 "That is not my job. My job is to</p> <p>2 examine the pathology so the clinician</p> <p>3 who worked up the patient, their</p> <p>4 decision was to remove the source of</p> <p>5 pain. And they identified source of</p> <p>6 pain in the mesh area. When I received</p> <p>7 the specimen there was nothing wrong.</p> <p>8 The only abnormality was mesh and</p> <p>9 tissue reaction to foreign body. The</p> <p>10 mesh itself was a disease in that</p> <p>11 specimen."</p> <p>12 Q. Move to strike everything after</p> <p>13 "that's not my job".</p> <p>14 Dr. Iakovlev, you don't know whether</p> <p>15 Ms. Ramirez had vaginal infections before 2010 do</p> <p>16 you?</p> <p>17 A. I don't remember now. If it was in</p> <p>18 the record I probably saw it but as I said, my</p> <p>19 focus and excised specimen.</p> <p>20 Q. And, Doctor, you don't know whether</p> <p>21 Ms. Ramirez had urinary tract infections before</p> <p>22 2010 do you?</p> <p>23 A. I don't remember now. Probably she</p> <p>24 had. People have them.</p>	<p>1 A. That's correct. That's what I just</p> <p>2 said.</p> <p>3 Q. And this medical record shows that</p> <p>4 Ms. Ramirez had pelvic pain before she received</p> <p>5 the TVT-O. Is that correct, sir?</p> <p>6 A. That's correct.</p> <p>7 Q. And, Doctor, you don't know if</p> <p>8 Ms. Ramirez had multiple exams after she received</p> <p>9 the TVT-O where she didn't complain of pain, do</p> <p>10 you?</p> <p>11 A. Yeah, she had some periods when</p> <p>12 there was no pain.</p> <p>13 Q. And, Doctor, before Ms. Ramirez</p> <p>14 received the TVT-O she also had another device</p> <p>15 called an Essure device implanted, is that</p> <p>16 correct?</p> <p>17 A. That's correct.</p> <p>18 Q. That's just basically another type</p> <p>19 of implant that she received in her pelvic area,</p> <p>20 is that right?</p> <p>21 MR. ANDERSON: Objection.</p> <p>22 THE DEPONENT: Yes, it was coils</p> <p>23 implanted in the uterus.</p> <p>24</p>

Vladimir Iakovlev, M.D.

Page 174	Page 176
<p>1 BY MR. HUTCHINSON:</p> <p>2 Q. And you don't know what the Essure</p> <p>3 device was made of do you?</p> <p>4 A. It's metal.</p> <p>5 Q. You don't know the type of metal do</p> <p>6 you?</p> <p>7 A. I don't know the specific type of</p> <p>8 metal.</p> <p>9 Q. And you don't know the rate of</p> <p>10 pelvic pain associated with this metal device in</p> <p>11 her pelvic area do you?</p> <p>12 A. No, I don't know the exact</p> <p>13 percentage.</p> <p>14 Q. And, Doctor, there will always be a</p> <p>15 foreign body response to any implant in the body,</p> <p>16 is that correct?</p> <p>17 A. Yes, it will be variable but there</p> <p>18 will be always a foreign body response.</p> <p>19 Q. That would include a medical -- a</p> <p>20 metal, M-E-T-A-L, I'm sorry, metal object wouldn't</p> <p>21 it?</p> <p>22 A. Yes, it will.</p> <p>23 Q. And it would include a TVT-O product</p> <p>24 wouldn't it, sir?</p>	<p>1 THE DEPONENT: Same answer.</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. Is it a yes or no? Can you tell us</p> <p>4 the name of the doctor who implanted the TVT-O</p> <p>5 device in Ms. Ramirez?</p> <p>6 A. I don't want to guess. I want to</p> <p>7 have record in front of me.</p> <p>8 Q. Is that a no?</p> <p>9 A. That was my answer.</p> <p>10 Q. Doctor, you didn't read any of the</p> <p>11 doctor depositions from Ms. Ramirez, did you?</p> <p>12 A. That's correct.</p> <p>13 Q. And you don't know what the</p> <p>14 implanting doctor said about how the sling was</p> <p>15 placed, do you?</p> <p>16 A. Well, I can see what was in the</p> <p>17 record at the time of implantation.</p> <p>18 Q. But my question is you don't know</p> <p>19 what the implanting doctor said in his deposition</p> <p>20 about where the sling was placed, do you?</p> <p>21 A. Not in deposition. Deposition</p> <p>22 happened years after implantation.</p> <p>23 Q. And you don't know what</p> <p>24 Ms. Ramirez's doctors said in their deposition</p>
Page 175	Page 177
<p>1 A. It would.</p> <p>2 Q. Now, let's talk about Ms. Ramirez's</p> <p>3 treating doctors for a minute. Dr. Reyes, he was</p> <p>4 the doctor who implanted the TVT-O, is that right?</p> <p>5 A. The document is not complete.</p> <p>6 Q. I'm not asking you a question about</p> <p>7 that document. I'm asking you whether or not you</p> <p>8 know the name of the doctor who implanted the TVT</p> <p>9 device in Ms. Ramirez?</p> <p>10 A. I don't remember all names. I mean,</p> <p>11 I review so many records I just don't want to</p> <p>12 guess. I want to read it from the record.</p> <p>13 Q. Did you ever make an effort to find</p> <p>14 out the name of the doctor who implanted the TVT</p> <p>15 device in Ms. Ramirez?</p> <p>16 MR. ANDERSON: Objection.</p> <p>17 THE DEPONENT: Of course. I review the</p> <p>18 record I see what's the name of the physician but</p> <p>19 I don't want to guess. I want to have records in</p> <p>20 front of me and read it from the record.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. And with you can't tell us that</p> <p>23 specific name now can you?</p> <p>24 MR. ANDERSON: Same objection.</p>	<p>1 about whether or not the mesh curled, do you?</p> <p>2 A. I don't know what was said.</p> <p>3 MS. VERBEEK: Objection to form.</p> <p>4 MR. ANDERSON: She objected.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. And let's talk about Dr. Graham. He</p> <p>7 was the doctor that did the revision surgery, is</p> <p>8 that correct?</p> <p>9 A. Again, I don't want do guess. I</p> <p>10 want to have excision operative report.</p> <p>11 Q. Can you tell us the name,</p> <p>12 Dr. Iakovlev, of the doctor who did Ms. Ramirez's</p> <p>13 revision surgery?</p> <p>14 MR. ANDERSON: Counsel, objection. As a</p> <p>15 matter of fairness if you want him to talk about</p> <p>16 the records put the records in front of him and</p> <p>17 stop the guessing game. We want to get to what he</p> <p>18 knows. Just put the records in front of him.</p> <p>19 MR. HUTCHINSON: Your objection is</p> <p>20 noted.</p> <p>21 MR. ANDERSON: Well, objection. It's</p> <p>22 not -- it's fundamental fairness. If you don't</p> <p>23 know and you don't have a memory game of</p> <p>24 everything in the records you can tell him that.</p>

45 (Pages 174 to 177)



Vladimir Iakovlev, M.D.

Page 178	Page 180
<p>1 THE DEPONENT: I don't want to play</p> <p>2 memory game or I don't want to guess. If we</p> <p>3 discuss the record I want to have record in front</p> <p>4 of me.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. And, Doctor, do you know when the</p> <p>7 doctor who did the revision surgery took out a 1</p> <p>8 centimeter piece of mesh?</p> <p>9 A. Again, I would like to see the</p> <p>10 explanting operative report. If we want to</p> <p>11 discuss specific details of the surgery I need to</p> <p>12 see the record.</p> <p>13 Q. And Doctor, if the record shows that</p> <p>14 on December 22nd, 2010, that some mesh was</p> <p>15 explanted would you have any reason to dispute</p> <p>16 that?</p> <p>17 MR. ANDERSON: Same objection.</p> <p>18 THE DEPONENT: Same objection. If you</p> <p>19 want to have specific numbers, specific dates,</p> <p>20 specific names I want to see the original record.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. Doctor, you didn't review the</p> <p>23 pathology from December of 2010, did you?</p> <p>24 A. You mean specimen?</p>	<p>1 A. Yes, he was.</p> <p>2 Q. And you remember his name but you</p> <p>3 don't remember the other doctor's names. Is that</p> <p>4 fair to say?</p> <p>5 MR. ANDERSON: Same objection.</p> <p>6 THE DEPONENT: Again, if we want to go</p> <p>7 to specific surgeries, to specific date, specific</p> <p>8 names I would like to see the record in front of</p> <p>9 me.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. And, Doctor, you know that Dr.</p> <p>12 Zimmern took out mesh in March of 2015, is that</p> <p>13 right?</p> <p>14 MR. ANDERSON: Objection.</p> <p>15 THE DEPONENT: I want to see the record.</p> <p>16 If we're discussing specific procedure I need to</p> <p>17 see the medical record.</p> <p>18 BY MR. HUTCHINSON:</p> <p>19 Q. Okay. And, Doctor, you looked at an</p> <p>20 explant that was taken out of Ms. Ramirez didn't</p> <p>21 you?</p> <p>22 A. Yes, I did.</p> <p>23 Q. And do you know the date that the</p> <p>24 explant was taken out of Ms. Ramirez?</p>
Page 179	Page 181
<p>1 Q. Yes.</p> <p>2 A. I believe there was no specimen, no</p> <p>3 pathological examination.</p> <p>4 Q. And you didn't read what Dr. Graham</p> <p>5 said about where or how the sling was placed in</p> <p>6 Ms. Ramirez, did you?</p> <p>7 A. You mean I did not read it in</p> <p>8 medical records or I did not --</p> <p>9 Q. No, the deposition.</p> <p>10 MR. ANDERSON: Objection. Go ahead.</p> <p>11 Asked and answered.</p> <p>12 THE DEPONENT: I told you I don't review</p> <p>13 depositions.</p> <p>14 BY MR. HUTCHINSON:</p> <p>15 Q. And you don't know what Dr. Graham</p> <p>16 said about whether or not the mesh curled do you,</p> <p>17 sir?</p> <p>18 MR. ANDERSON: Objection.</p> <p>19 THE DEPONENT: I gave you an answer. I</p> <p>20 review what is in the records. I don't review</p> <p>21 depositions.</p> <p>22 BY MR. HUTCHINSON:</p> <p>23 Q. Dr. Zimmern, he was another doctor</p> <p>24 that did a surgery wasn't he?</p>	<p>1 A. It was March 2015. Exact day, again</p> <p>2 I would have to check with my -- so it was March</p> <p>3 10th, 2015.</p> <p>4 Q. And you never saw the mesh when it</p> <p>5 was in Ms. Ramirez's body did you, sir?</p> <p>6 A. No.</p> <p>7 Q. And if Dr. Zimmern testified under</p> <p>8 oath that the mesh was flat when he took it out</p> <p>9 you'd disagree with him wouldn't you?</p> <p>10 MR. ANDERSON: Objection.</p> <p>11 THE DEPONENT: One part was definitely</p> <p>12 not flat. That's how it works in medicine,</p> <p>13 treating physicians they have their opinions but</p> <p>14 pathologists can find something else. I mean,</p> <p>15 otherwise we wouldn't be employed in the hospital.</p> <p>16 We wouldn't be needed.</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. Move to strike as nonresponsive.</p> <p>19 My question, Doctor, if Dr. Zimmern</p> <p>20 testified under oath that the mesh was flat when</p> <p>21 he took it out you'd disagree with him wouldn't</p> <p>22 you?</p> <p>23 MR. ANDERSON: Objection to form. Asked</p> <p>24 and answered. Go ahead.</p>

46 (Pages 178 to 181)

Vladimir Iakovlev, M.D.

Page 182	Page 184
<p>1 THE DEPONENT: I would and it's a pretty</p> <p>2 common situation when pathologists disagree on</p> <p>3 some points with the clinicians.</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. And if Dr. Zimmern testified there</p> <p>6 was no evidence of fraying or curling you'd</p> <p>7 disagree with him wouldn't you, sir?</p> <p>8 MR. ANDERSON: Same objection.</p> <p>9 THE DEPONENT: I would.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Is that a yes?</p> <p>12 A. Yes, I would disagree with him.</p> <p>13 Q. And you don't know if photographs</p> <p>14 that were taken of the mesh out of Ms. Ramirez's</p> <p>15 surgery -- strike that.</p> <p>16 Dr. Iakovlev, you don't know if</p> <p>17 photographs were taken of the mesh after her</p> <p>18 surgery do you?</p> <p>19 A. No, I don't remember seeing them.</p> <p>20 Maybe they were in the records, maybe not. I</p> <p>21 don't remember them.</p> <p>22 Q. But you never looked at the</p> <p>23 photographs did you?</p> <p>24 A. I could have. But I had my</p>	<p>1 ---DEFENSE EXHIBIT NO. 3: Patient</p> <p>2 record from UT Southwestern Medical</p> <p>3 Center re. Jennifer Ramirez, printed on</p> <p>4 4/6/2015. Bates labelled</p> <p>5 RAMIREZJ_UTSMC_MDR00311.</p> <p>6 BY MR. HUTCHINSON:</p> <p>7 Q. But before we go there your</p> <p>8 specialty is not reviewing ultrasounds, is that</p> <p>9 correct?</p> <p>10 A. No, that's correct. I am not</p> <p>11 reviewing ultrasounds.</p> <p>12 Q. Are you on Exhibit 3 with me?</p> <p>13 A. Yes, I am.</p> <p>14 Q. And this is the biopsy, surgical</p> <p>15 specimen report that we have in front of you, is</p> <p>16 that right?</p> <p>17 A. That's correct.</p> <p>18 Q. This was part of the documents you</p> <p>19 reviewed in forming your opinions, is that right?</p> <p>20 A. That it is.</p> <p>21 Q. And this was a document prepared by</p> <p>22 the doctors who saw Ms. Ramirez over in Texas, is</p> <p>23 that right?</p> <p>24 MR. ANDERSON: Objection.</p>
Page 183	Page 185
<p>1 specimen, my own specimen and I examined it</p> <p>2 grossly, I examined it microscopically.</p> <p>3 Q. And you don't know if there was an</p> <p>4 ultrasound take of the mesh when it was in her</p> <p>5 body do you, sir?</p> <p>6 A. I think it was taken at one point.</p> <p>7 Q. And you never looked at the</p> <p>8 ultrasound did you, sir?</p> <p>9 A. Ultrasound pictures or ultrasound</p> <p>10 report?</p> <p>11 Q. No, the ultrasound pictures. That's</p> <p>12 something that you never reviewed, is that</p> <p>13 correct?</p> <p>14 A. Again, if they were in the records I</p> <p>15 probably saw them. Well, I definitely saw</p> <p>16 everything which was in the records but I'm not a</p> <p>17 radiologist and I don't normally look at them in</p> <p>18 my day-to-day practice.</p> <p>19 Q. But if there were an ultrasound that</p> <p>20 you remember you couldn't interpret it could you?</p> <p>21 A. I can interpret it to a degree, not</p> <p>22 as well as a radiologist but I can interpret some.</p> <p>23 Q. Doctor, I want to hand you what</p> <p>24 we'll mark as Exhibit 3 to your deposition.</p>	<p>1 THE DEPONENT: Well it is a pathology</p> <p>2 report.</p> <p>3 BY MR. HUTCHINSON:</p> <p>4 Q. Pathologists are doctors aren't</p> <p>5 they, sir?</p> <p>6 A. Yes, but they don't see patients.</p> <p>7 At least most of the patients are not seen by</p> <p>8 pathologists when they examine the specimens.</p> <p>9 Sometimes we do see patients but most of the time,</p> <p>10 and I believe for that specific case the</p> <p>11 pathologist did not see Ms. Ramirez.</p> <p>12 Q. And, Doctor, let's look under "Final</p> <p>13 Pathologic Diagnosis"?</p> <p>14 A. Yes.</p> <p>15 Q. Of what the doctors from the UT</p> <p>16 Southwestern Medical Center found. Are you there</p> <p>17 with me?</p> <p>18 A. Yes, I am.</p> <p>19 Q. They didn't find any degradation did</p> <p>20 they?</p> <p>21 A. No, they didn't examine it.</p> <p>22 Q. And they didn't find any particle</p> <p>23 loss did they?</p> <p>24 A. They didn't examine for degradation</p>

47 (Pages 182 to 185)

Vladimir Iakovlev, M.D.

Page 186	Page 188
<p>1 or particle loss.</p> <p>2 Q. In fact these doctors from Texas</p> <p>3 didn't find any mesh deformation did they, sir?</p> <p>4 A. There is no description of</p> <p>5 deformation or nondeformation.</p> <p>6 Q. And, Doctor, I want to hand you what</p> <p>7 we'll mark as Exhibit 4 to your deposition.</p> <p>8 ---DEFENSE EXHIBIT NO. 4: Surgical</p> <p>9 pathology report from St. Michael's</p> <p>10 Hospital re. Jennifer Ramirez dated</p> <p>11 10/5/2015.</p> <p>12 BY MR. HUTCHINSON:</p> <p>13 Q. You did your own surgical</p> <p>14 pathological report here in Canada for Ms.</p> <p>15 Ramirez, didn't you, sir?</p> <p>16 A. That's correct.</p> <p>17 Q. And this is a copy of it?</p> <p>18 A. Yes, it is.</p> <p>19 Q. And under "Final Diagnosis" there in</p> <p>20 the middle, are you there with me?</p> <p>21 A. Yes.</p> <p>22 Q. You didn't find any degradation</p> <p>23 under your final diagnosis for Ms. Ramirez did</p> <p>24 you, sir?</p>	<p>1 A. Possible.</p> <p>2 Q. Or specimen?</p> <p>3 A. I don't remember how many pictures I</p> <p>4 took.</p> <p>5 Q. Well, why don't you look at your</p> <p>6 report. Your report includes 19 pictures labelled</p> <p>7 JR(1) through JR(19). Is that correct, sir?</p> <p>8 A. Yeah, except some of them combine</p> <p>9 too so it's over 19.</p> <p>10 Q. Over 19, is that right?</p> <p>11 A. At least 19, yes.</p> <p>12 Q. And none of these 19 pictures show</p> <p>13 any particle loss from the mesh. Is that correct,</p> <p>14 sir?</p> <p>15 A. That's correct. No visible particle</p> <p>16 loss. I mean, it has to be visible in order for</p> <p>17 me to see in the microscope. If it's smaller than</p> <p>18 what can be seen then I cannot detect them.</p> <p>19 Q. Move to strike everything after</p> <p>20 other than, yes, "that's correct".</p> <p>21 MR. ANDERSON: He answered your</p> <p>22 question.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. And, Dr. Iakovlev, you're not</p>
Page 187	Page 189
<p>1 A. I think that's incorrect.</p> <p>2 Q. Doctor, will you show the jury --</p> <p>3 hold this up and publish it to the jury please?</p> <p>4 MR. ANDERSON: Objection.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. I'm sorry, I'm still working on my</p> <p>7 question. Dr. Iakovlev, you didn't find that</p> <p>8 there was any degradation from Ms. Ramirez's mesh</p> <p>9 in your final diagnosis did you, sir?</p> <p>10 A. Yes, I did. That's what it says.</p> <p>11 "Surgical knitted monofilament mesh with</p> <p>12 associated tissue changes. Please see synoptic</p> <p>13 data for details." Then details expand and the</p> <p>14 degradation layer is described there and it's</p> <p>15 measured on the second page.</p> <p>16 Q. Doctor, you didn't find any particle</p> <p>17 loss for Ms. Ramirez did you?</p> <p>18 A. Not visible large particles, that's</p> <p>19 correct. I could not examine for smaller</p> <p>20 particles which I could not see, but I could not</p> <p>21 rule them out.</p> <p>22 Q. And in fact, Doctor, you took 19</p> <p>23 photographs of Ms. Ramirez's mesh, is that</p> <p>24 correct?</p>	<p>1 telling the jury that there are any loose</p> <p>2 particles from the mesh in Ms. Ramirez's tissue,</p> <p>3 are you?</p> <p>4 MR. ANDERSON: Objection, asked and</p> <p>5 answered.</p> <p>6 THE DEPONENT: I did not show it in the</p> <p>7 specimen.</p> <p>8 BY MR. HUTCHINSON:</p> <p>9 Q. And in fact, Doctor, you don't know</p> <p>10 if Ms. Ramirez's mesh was mechanically cut or</p> <p>11 laser cut, do you?</p> <p>12 A. No, I don't.</p> <p>13 Q. And, Doctor, let's look at Exhibit</p> <p>14 4(B)?</p> <p>15 A. You mean 4(B) from my --</p> <p>16 Q. From your direct examination. I'm</p> <p>17 going to ask that you show it up on the screen</p> <p>18 please. Exhibit 4(B).</p> <p>19 A. Yes.</p> <p>20 Q. This is some of the light microscopy</p> <p>21 work that you did for Ms. Ramirez's mesh, is that</p> <p>22 right?</p> <p>23 A. No, this is not right.</p> <p>24 Q. This is Ms. Ramirez's mesh explant</p>

48 (Pages 186 to 189)

Vladimir Iakovlev, M.D.

Page 190	Page 192
<p>1 isn't it, sir?</p> <p>2 A. That's correct.</p> <p>3 Q. And in fact you can't tell us which</p> <p>4 piece of mesh would have come out of her left side</p> <p>5 or right side, can you?</p> <p>6 A. Yes, I can.</p> <p>7 Q. Doctor, I want to hand you your</p> <p>8 deposition transcript and direct your attention to</p> <p>9 page 53, line 7. Are you there with me</p> <p>10 Dr. Iakovlev?</p> <p>11 A. Yes. Let me read the page and then</p> <p>12 we will come back to it.</p> <p>13 Q. Have you finished reading it,</p> <p>14 Dr. Iakovlev?</p> <p>15 A. Yes, I did.</p> <p>16 Q. And, Dr. Iakovlev, you raised your</p> <p>17 right-hand and promised to tell the truth on this</p> <p>18 time didn't you?</p> <p>19 MR. ANDERSON: Objection. You've</p> <p>20 already asked and answered if he knew he was under</p> <p>21 oath. He said he was under oath did. Stop</p> <p>22 beating him up. Don't answer the question.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. Dr. Iakovlev, are you refusing to</p>	<p>1 BY MR. HUTCHINSON:</p> <p>2 Q. Dr. Iakovlev --</p> <p>3 MR. ANDERSON: If you want to ask him a</p> <p>4 question that's just like that question then</p> <p>5 that's fine. That's a different question and you</p> <p>6 know it.</p> <p>7 BY MR. HUTCHINSON:</p> <p>8 Q. Dr. Iakovlev, did I read that</p> <p>9 question and answer correctly, sir?</p> <p>10 A. You did not read the complete</p> <p>11 answers but you read that part. Because there is</p> <p>12 an answer I just gave before that, you repeated</p> <p>13 the question during deposition. And my -- can I</p> <p>14 answer that?</p> <p>15 MR. ANDERSON: Yes.</p> <p>16 THE DEPONENT: So my answer was it would</p> <p>17 be difficult to determine with certainty. So I</p> <p>18 would need -- and then there is explanation.</p> <p>19 Clinically there were some other studies it could</p> <p>20 explain that. So combining clinical information</p> <p>21 and my pathological I can tell you which one is</p> <p>22 left and which 1 is right, but if I don't have</p> <p>23 clinical information just pathology it would be</p> <p>24 difficult for me.</p>
Page 191	Page 193
<p>1 answer that question.</p> <p>2 MR. FREESE: Yes, he's being instructed</p> <p>3 not to answer it. It's argumentative and he</p> <p>4 understands he's under oath.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. Dr. Iakovlev, page 53, line 7 it</p> <p>7 says:</p> <p>8 "As we sit here today you cannot tell</p> <p>9 us which piece of the explant would go</p> <p>10 in the left-hand side or in the middle</p> <p>11 side?</p> <p>12 "ANSWER: Not from what I have in the</p> <p>13 specimen. I mean, if clinically there</p> <p>14 was some other studies it could explain</p> <p>15 that. It would be hard. Also I don't</p> <p>16 know if it was divided before."</p> <p>17 Did I read that correctly, sir?</p> <p>18 MR. ANDERSON: Objection. Inappropriate</p> <p>19 impeachment. That is a different question than</p> <p>20 you just asked him before so it's an unfair</p> <p>21 re-reading.</p> <p>22 MR. HUTCHINSON: No it's not.</p> <p>23 MR. ANDERSON: Yeah, it is. It's an</p> <p>24 inappropriate way to impeach him.</p>	<p>1 BY MR. HUTCHINSON:</p> <p>2 Q. Move to strike as nonresponsive.</p> <p>3 Doctor, let's look at the photographs</p> <p>4 that you took labelled J(1) through J(5).</p> <p>5 MR. ANDERSON: What are you referring</p> <p>6 to?</p> <p>7 MR. HUTCHINSON: In your expert report.</p> <p>8 MR. ANDERSON: You mean in defendant's</p> <p>9 Exhibit 1.</p> <p>10 MR. HUTCHINSON: Correct.</p> <p>11 BY MR. HUTCHINSON:</p> <p>12 Q. Are you there, Dr. Iakovlev?</p> <p>13 A. Yes, I am.</p> <p>14 Q. You can't tell us whether the mesh</p> <p>15 was curling at the time it was taken out can you,</p> <p>16 sir?</p> <p>17 A. I can.</p> <p>18 Q. I'm sorry?</p> <p>19 A. I can. It was curled inside the</p> <p>20 body.</p> <p>21 Q. Dr. Iakovlev, let's look back at</p> <p>22 your deposition. And by the way, before we do</p> <p>23 that, you can't tell the jury whether the mesh was</p> <p>24 curling at the time it was implanted can you?</p>

49 (Pages 190 to 193)

Vladimir Iakovlev, M.D.

Page 194	Page 196
<p>1 A. No, I cannot tell that. It curled 2 sometime in the body. 3 Q. But you can't tell us whether or not 4 it curled at the time it was taken out can you? 5 MR. ANDERSON: Objection, asked and 6 answered. 7 THE DEPONENT: What do you mean? It was 8 curled only during excision not while it was in 9 the body? I can tell you it was curled up before 10 the scar tissue could grow into the curl. This is 11 very obvious in the images. It curled up in the 12 body and the lumen inside the curl was filled with 13 the scar tissue. This can happen only in the 14 body. This cannot happen during the excision. 15 You cannot make scar grow inside the mesh during 16 the excision. 17 BY MR. HUTCHINSON: 18 Q. Move to strike as nonresponsive. 19 Dr. Iakovlev, you cannot say whether the 20 curling occurred at the time of implantation or 21 post implantation, can you? 22 MR. ANDERSON: Objection to form. 23 Compound, asked and answered and form. 24 MS. VERBEEK: Same objection.</p>	<p>1 density for Ms. Ramirez did you? 2 A. It's not needed for my opinions. 3 Q. Move to strike as nonresponsive. My 4 question is asking for a yes or no please. 5 Dr. Iakovlev, you didn't count the nerve 6 density for Ms. Ramirez did you, sir? 7 A. Because it was not required for my 8 opinions I did not count it. 9 Q. Move to strike everything after "I 10 did not" -- I mean, before "I did not count it". 11 Dr. Iakovlev, in fact you didn't consult 12 with a neuropathologist regarding Ms. Ramirez's 13 case, did you? 14 A. I didn't need to. 15 Q. And, Doctor, if we look at Exhibit 16 4, which is the report that you created in Canada, 17 are we on the same page? 18 MR. ANDERSON: Objection to form. 19 THE DEPONENT: Yes, we are. 20 BY MR. HUTCHINSON: 21 Q. Doctor, look at the bottom for me 22 please. It says "synoptic diagnosis". Did I read 23 that correctly? 24 A. Yes, you did.</p>
Page 195	Page 197
<p>1 THE DEPONENT: As I told you I cannot. 2 MR. HUTCHINSON: Why don't we take a 3 quick break. 4 THE VIDEOGRAPHER: Going off the record 5 at 1:48 p.m. 6 --- Break taken. 7 THE VIDEOGRAPHER: We're back on the 8 record at 1:55 p.m. 9 BY MR. HUTCHINSON: 10 Q. Dr. Iakovlev, let's talk about 11 nerves for a minute okay? 12 A. Okay. 13 Q. And the TVT-O would have gone 14 through Ms. Ramirez's transobturator space, is 15 that correct? 16 A. That's correct. 17 Q. And nerves come in different shapes 18 and they come in different sizes? 19 A. I'm not sure about shape but, yes, 20 they have different caliber. The trunk starts 21 thicker and the branches branch off. They are 22 thinner and thinner and everything gets thinner 23 and thinner. 24 Q. Doctor, you didn't count the nerve</p>	<p>1 Q. And in fact under synoptic diagnosis 2 it says, "Acute inflammation: No." Did I read 3 that correctly? 4 A. Yes, you read it correctly. 5 Q. And it says, "Nerve branch 6 count/tissue area." 7 A. That's correct. 8 Q. And then under that it says, "All 9 tissue". Do you see that? 10 A. Yes, I do. 11 Q. And, Doctor, you write, "Cannot do 12 formal count in a limited specimen." 13 A. That's correct. 14 Q. Did I read that correctly? 15 A. Yes, you did read it correctly. 16 Q. In fact, Doctor, you have not 17 identified any nerve receptors in Ms. Ramirez's 18 slides have you? 19 A. Are we now switching from nerves to 20 nerve receptors? 21 Q. That's correct. 22 A. Because I was not looking for 23 receptors I was looking for nerves. There are no 24 nerves without receptors, or most of them will</p>

50 (Pages 194 to 197)



Vladimir Iakovlev, M.D.

Page 198	Page 200
<p>1 have receptors. The only time they don't have</p> <p>2 receptors is when they end up with traumatic</p> <p>3 neuroma.</p> <p>4 Q. And Doctor, you'll agree that pain</p> <p>5 receptors are usually just bare endings of nerves,</p> <p>6 is that correct?</p> <p>7 A. Most of them are.</p> <p>8 Q. And those are called nociceptors, is</p> <p>9 that correct?</p> <p>10 A. That's another term for pain</p> <p>11 receptors.</p> <p>12 Q. Am I correct, Doctor?</p> <p>13 A. You're correct.</p> <p>14 Q. You need a stain to detect a</p> <p>15 nociceptor don't you, sir?</p> <p>16 A. You need to stain for anything in</p> <p>17 histology. So you need to stain specifically for</p> <p>18 anything.</p> <p>19 Q. And in fact the specific chemical</p> <p>20 that you need to use to stain for a nociceptor is</p> <p>21 something called PGP9.5. Is that correct, sir?</p> <p>22 A. One of it. It can be used for a</p> <p>23 nerve -- for axons.</p> <p>24 Q. And you showed the jury a lot of</p>	<p>1 causing pain can you?</p> <p>2 A. As I said, most of the nerves are</p> <p>3 mixed therefore most of the nerves deliver or</p> <p>4 conduct pain signals. So when I look at a nerve,</p> <p>5 any nerve in the body, to a reasonable degree of</p> <p>6 medical certainty, it does conduct pain signals.</p> <p>7 Q. You can only estimate the</p> <p>8 probabilities can't you, sir?</p> <p>9 A. Yes.</p> <p>10 Q. And, Doctor, when we talk about</p> <p>11 neuromas that's a painful condition also known as</p> <p>12 a pinched nerve, is that right?</p> <p>13 A. No, it is not. It is different</p> <p>14 lesion. Both can cause pain, traumatic neuroma or</p> <p>15 pinched nerve but they are different lesions.</p> <p>16 Q. And, Dr. Iakovlev, you're not</p> <p>17 telling this jury that Ms. Ramirez had any</p> <p>18 neuromas are you, sir?</p> <p>19 A. I did not see them in the slides but</p> <p>20 I cannot rule them out. I see them all the time</p> <p>21 in mesh specimens. They could have not been just</p> <p>22 sampled.</p> <p>23 Q. And, Doctor -- move to strike as</p> <p>24 nonresponsive.</p>
Page 199	Page 201
<p>1 slides from Ms. Ramirez this morning, didn't you,</p> <p>2 sir?</p> <p>3 A. Yes, I did.</p> <p>4 Q. And you didn't stain one of those</p> <p>5 with PGP9.5 stain did you, sir?</p> <p>6 A. Well, I use neurofilament it's</p> <p>7 almost the same stain. It stains the same</p> <p>8 structures.</p> <p>9 Q. Move to strike as nonresponsive.</p> <p>10 MR. ANDERSON: Well. He answered your</p> <p>11 question.</p> <p>12 BY MR. HUTCHINSON:</p> <p>13 Q. My question, sir, is that you didn't</p> <p>14 stain any of Ms. Ramirez's slides with the stain</p> <p>15 PGP9.5. Yes or no?</p> <p>16 A. Well, sounds like you're teaching me</p> <p>17 pathology what I should and what I should not have</p> <p>18 used. I used neurofilament which is similar stain</p> <p>19 to PGP, this will answer. But I did not use</p> <p>20 PGP9.5.</p> <p>21 Q. Move to strike everything before "I</p> <p>22 did not use PGP9.5".</p> <p>23 In fact, Doctor, you can't look at a</p> <p>24 nerve on a slide and tell whether or not it's</p>	<p>1 Tissue necrosis that's the same thing as</p> <p>2 dead tissue isn't it?</p> <p>3 A. That's correct.</p> <p>4 Q. And not one of the slides that you</p> <p>5 showed the jury showed any tissue necrosis did</p> <p>6 they?</p> <p>7 A. No, they did not.</p> <p>8 Q. In fact let's be crystal clear. You</p> <p>9 saw no dead tissue from Ms. Ramirez in your work</p> <p>10 in this case, is that correct?</p> <p>11 A. No, I didn't.</p> <p>12 Q. Doctor, I'm going to hand you what</p> <p>13 we'll mark as Exhibit 5 to your deposition.</p> <p>14 ---DEFENSE EXHIBIT NO. 5: Diagram</p> <p>15 depicting the female anatomy after a</p> <p>16 hysterectomy is done.</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. We know that Ms. Ramirez had a</p> <p>19 hysterectomy don't we?</p> <p>20 A. Yes, we do.</p> <p>21 Q. And Dr. Iakovlev, would you show</p> <p>22 that picture to the jury? This diagram shows the</p> <p>23 female anatomy after a hysterectomy is done, is</p> <p>24 that correct?</p>

51 (Pages 198 to 201)

Vladimir Iakovlev, M.D.

Page 202	Page 204
<p>1 A. That's correct.</p> <p>2 Q. And you can't tell the jury where on</p> <p>3 that diagram that Ms. Ramirez experienced pain can</p> <p>4 you?</p> <p>5 MR. ANDERSON: Objection to form.</p> <p>6 THE DEPONENT: Well, this diagram</p> <p>7 describes a hypothetical patient it does not</p> <p>8 represent Ms. Ramirez. I don't see ovaries here,</p> <p>9 because she still has ovaries in her body and this</p> <p>10 diagram doesn't depict them. She has TVT mesh</p> <p>11 sling and it doesn't depict them so this diagram</p> <p>12 doesn't represent Ms. Ramirez.</p> <p>13 BY MR. HUTCHINSON:</p> <p>14 Q. Move to strike as nonresponsive.</p> <p>15 Dr. Iakovlev, show the jury that picture</p> <p>16 and you can't tell the jury where Ms. Ramirez</p> <p>17 experienced pain in her anatomy can you, sir?</p> <p>18 MR. ANDERSON: Objection. Asked and</p> <p>19 answered. Go ahead, answer it again.</p> <p>20 THE DEPONENT: So my answer is that this</p> <p>21 diagram does not represent Ms. Ramirez. And I</p> <p>22 just listed you all the reasons why it does not</p> <p>23 represent Ms. Ramirez therefore we cannot use this</p> <p>24 exhibit to demonstrate any anatomical features.</p>	<p>1 MR. ANDERSON: Objection, asked and</p> <p>2 answered. I think we're at three times now. I</p> <p>3 can probably read it back, but answer it one more</p> <p>4 time and that's it.</p> <p>5 THE DEPONENT: This diagram does not</p> <p>6 represent Ms. Ramirez's anatomy therefore I will</p> <p>7 not use this diagram for any demonstrations.</p> <p>8 BY MR. HUTCHINSON:</p> <p>9 Q. Move to strike as nonresponsive.</p> <p>10 Doctor, yes or no, can you show the jury</p> <p>11 on that diagram where Ms. Ramirez experienced</p> <p>12 pain.</p> <p>13 MR. ANDERSON: Same objection. And if</p> <p>14 you keep being rude to him and trying to beat him</p> <p>15 up we're going to stop it.</p> <p>16 MR. HUTCHINSON: I'm not being rude.</p> <p>17 MR. ANDERSON: Yeah, you are. Asking</p> <p>18 the same question over and over is rude and</p> <p>19 disrespectful.</p> <p>20 BY MR. HUTCHINSON:</p> <p>21 Q. Dr. Iakovlev, you can answer the</p> <p>22 question.</p> <p>23 MR. ANDERSON: Asked and answered. Same</p> <p>24 answer.</p>
Page 203	Page 205
<p>1 BY MR. HUTCHINSON:</p> <p>2 Q. Dr. Iakovlev, I want to hand you a</p> <p>3 black marker and why don't you draw the ovaries on</p> <p>4 that diagram for us please, sir?</p> <p>5 MR. ANDERSON: Objection.</p> <p>6 THE DEPONENT: I don't want to use this</p> <p>7 diagram because it does not represent Ms. Ramirez.</p> <p>8 BY MR. HUTCHINSON:</p> <p>9 Q. Are you refusing to draw the ovaries</p> <p>10 on that diagram?</p> <p>11 A. Well, it implies that I will try to</p> <p>12 make it fit Ms. Ramirez's anatomy but I cannot do</p> <p>13 that.</p> <p>14 Q. Move to strike as nonresponsive.</p> <p>15 Are you refusing to draw ovaries on that</p> <p>16 diagram, Dr. Iakovlev?</p> <p>17 MR. ANDERSON: Same objection.</p> <p>18 THE DEPONENT: I will not use a diagram</p> <p>19 which does to the represent the patient whose</p> <p>20 specimen I examined.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. Doctor, you can't show the jury on</p> <p>23 that diagram where Ms. Ramirez experienced pain</p> <p>24 can you?</p>	<p>1 MR. HUTCHINSON: Your objection is</p> <p>2 noted, counsel.</p> <p>3 MR. ANDERSON: I know it is. Go ahead.</p> <p>4 THE DEPONENT: I cannot demonstrate</p> <p>5 Ms. Ramirez's anatomy on this diagram because it</p> <p>6 does not represent Ms. Ramirez.</p> <p>7 BY MR. HUTCHINSON:</p> <p>8 Q. Dr. Iakovlev, I want to hand you</p> <p>9 what we've mark as Exhibit 6 to your deposition.</p> <p>10 ---DEFENSE EXHIBIT NO. 6: Diagram</p> <p>11 depicting the muscles in the female</p> <p>12 pelvic floor.</p> <p>13 BY MR. HUTCHINSON:</p> <p>14 Q. This diagram shows the muscles in</p> <p>15 the female pelvic floor doesn't it, sir?</p> <p>16 A. That's correct.</p> <p>17 Q. Would you show it to the jury</p> <p>18 please? You can't show the jury where Ms. Ramirez</p> <p>19 experienced pain on this diagram can you?</p> <p>20 MR. ANDERSON: Objection.</p> <p>21 THE DEPONENT: The answer would be</p> <p>22 similar. This diagram actually shows depth of the</p> <p>23 body around the vagina when the nerves are</p> <p>24 completely removed. When all the tissue where</p>

52 (Pages 202 to 205)

Vladimir Iakovlev, M.D.

Page 206	Page 208
<p>1 Ms. Ramirez was experiencing pain, or partially, 2 is removed from this tissue. You can see stumps 3 of the nerves sticking out from behind the bone so 4 it does not represent again the situation 5 Ms. Ramirez was in. 6 BY MR. HUTCHINSON: 7 Q. Move to strike as nonresponsive. 8 Dr. Iakovlev, show the jury that 9 photograph please. And tell the jury where on 10 that photograph that Ms. Ramirez experienced pain? 11 MR. ANDERSON: Objection, asked and 12 answered. 13 THE DEPONENT: So my answer will be that 14 this diagram shows partially dissected human body 15 when the nerves, which are supplying innervation 16 in the area of vagina, are partially removed in 17 the tissue. So that tissue which was experiencing 18 pain, or Ms. Ramirez's tissue, was removed in the 19 graphics. And you can see stumps of the nerves 20 and the vessels sticking from behind the bone. So 21 this does not represent Ms. Ramirez's anatomy 22 either at the time of explantation or now. 23 BY MR. HUTCHINSON: 24 Q. Move to strike as nonresponsive.</p>	<p>1 A. To a degree. 2 Q. And in order to find pain the 3 patient has to tell you there's pain doesn't she? 4 A. Yes. 5 Q. And you've never talked with 6 Ms. Ramirez in this case have you, sir? 7 A. That's correct. 8 Q. So, Doctor, I want to talk about 9 foreign body reaction and inflammation as it 10 relates to pain. Okay? 11 A. Okay. 12 Q. Changing gears a bit. It's my 13 understanding you think there is a higher degree 14 of inflammation associated with high rates of 15 pain. Am I right? 16 A. My answer would be that inflammation 17 is one of the factors in the mechanisms of pain. 18 It changes threshold of sensitivity of the 19 tissues. And we all know that inflamed tissue is 20 painful. So that known fact. 21 Q. Doctor, you know that there's some 22 literature that disagrees with you on that don't 23 you? 24 MR. ANDERSON: Objection, form.</p>
Page 207	Page 209
<p>1 Dr. Iakovlev, you can't show the jury 2 where Ms. Ramirez experienced pain on that diagram 3 can you? 4 MR. ANDERSON: Objection. Asked and 5 answered. I think -- 6 BY MR. HUTCHINSON: 7 Q. I'm asking for a yes or no. 8 MR. ANDERSON: Don't interrupt me 9 please. That's like three times you've asked the 10 same question and you can get the same answer if 11 you want. 12 BY MR. HUTCHINSON: 13 Q. Yes or no, Dr. Iakovlev? 14 A. This diagram does not represent 15 Ms. Ramirez's anatomy. 16 Q. Can you answer that question yes or 17 no? 18 MR. ANDERSON: Objection, asked and 19 answered. 20 THE DEPONENT: I'm giving you the best 21 answer I have. 22 BY MR. HUTCHINSON: 23 Q. Doctor, we know that pain is a 24 subjective complaint don't we?</p>	<p>1 BY MR. HUTCHINSON: 2 Q. Dr. Iakovlev you know there's some 3 literature -- 4 THE VIDEOGRAPHER: Going off the record 5 at 2:09 p.m. 6 --- Break taken. 7 THE VIDEOGRAPHER: We're back on the 8 record at 2:10 p.m. 9 BY MR. HUTCHINSON: 10 Q. Doctor, before we went off the 11 record my question was, you know there's some 12 literature that disagrees with you don't you, sir? 13 A. Specifically what part of my 14 statement would be described in the literature as 15 in opposite -- with opposite conclusions? 16 Q. We're going to talk about your 17 conclusion that inflammation is associated with 18 high rates of pain. 19 MR. ANDERSON: Is that a question. 20 BY MR. HUTCHINSON: 21 Q. I'm going to finish my question. I 22 want to hand you Exhibit 7. 23 ---DEFENSE EXHIBIT NO. 7: Article 24 titled "Histopathology of excised</p>

Vladimir Iakovlev, M.D.

Page 210	Page 212
<p>1 midurethral sling mesh", found in the 2 International Urogynecology Journal, 3 2015. 4 BY MR. HUTCHINSON: 5 Q. This is the Hill paper, is that 6 correct? 7 A. Yes, okay. Sorry. You're correct. 8 Q. And you don't think the Hill paper 9 is funny do you? 10 MR. ANDERSON: Something happened off 11 the record. Don't do that, counsel. 12 MR. HUTCHINSON: I'm sorry, I'll 13 withdraw the question. I thought you were 14 laughing about the Hill paper. 15 MR. ANDERSON: Well I could but I wasn't 16 there. 17 BY MR. HUTCHINSON: 18 Q. Dr. Iakovlev, you have in front high 19 of you the Hill paper entitled "Histopathology of 20 excised midurethral sling mesh". Is that correct? 21 A. That's correct. 22 Q. And you're familiar with this 23 article, aren't you? 24 A. Yes, I am.</p>	<p>1 He's not a urogynecologist or a gynecologist, so 2 stipulated. Let's not keep asking the same 3 question. 4 MR. HUTCHINSON: 5 Q. Dr. Iakovlev? 6 A. Yeah, the answer is I'm not a 7 urogynecologist I'm a pathologist. 8 Q. And you would consider this a 9 reputable organization wouldn't you? 10 A. Yes, I would. 11 Q. And you read and rely on articles 12 from this same journal don't you? 13 A. Yes. 14 Q. And in fact you consider it 15 authoritative in its field don't you, sir? 16 A. Yes. 17 Q. And the authors of this Hill paper 18 are from the Cleveland Clinic here in the United 19 States. You understand that don't you, sir? 20 A. Yes, they are. 21 Q. And the people who wrote this 22 article were pathologists just like yourself, is 23 that right? 24 MR. ANDERSON: Objection.</p>
Page 211	Page 213
<p>1 Q. And it was published by the 2 International Urogynecological Journal, is that 3 right? 4 A. That's correct. 5 Q. And that's the official journal of 6 the International Urogynecological Association, is 7 that right? 8 A. I don't know if it's one -- the 9 official one but it's a journal in 10 urogynecological field of medicine. 11 Q. And you're familiar with that 12 association aren't you, sir. 13 A. Yes, I am. 14 Q. And that's an organization made up 15 of urogynecologists all over the world, isn't it? 16 A. Yes, it is. 17 Q. And the focus of their practice is 18 treating gynecological issues, is that right? 19 A. That's correct. 20 Q. And that's much different than 21 yours. Is that correct, sir? You're not a 22 urologist or a urogynecologist, is that correct? 23 MR. ANDERSON: Objection. That's been 24 asked two or three times. He's a pathologist.</p>	<p>1 THE DEPONENT: One of them. 2 BY MR. HUTCHINSON: 3 Q. And that's the one from the 4 Cleveland Clinic. Is that right, sir? 5 A. Well, I think they're all from 6 Cleveland Clinic or from Cleveland. He's from 7 Cleveland Clinic. 8 Q. Thank you. And, Dr. Iakovlev -- 9 A. Actually not he, she is from 10 Cleveland Clinic, sorry. 11 Q. Dr. Iakovlev, the conclusion of this 12 Hill study was that mesh taken out for non-pain 13 reasons has more inflammation than mesh taken out 14 because of pain. That's the conclusion of this 15 study. Is that right, sir? 16 MR. ANDERSON: Objection. 17 THE DEPONENT: Well, if you want me to 18 read conclusions I would have to read the 19 conclusions. 20 BY MR. HUTCHINSON: 21 Q. Well, my question to you, sir, in a 22 nutshell, when we talk about the conclusion of the 23 Hill study that's what these authors concluded, is 24 that correct?</p>

Vladimir Iakovlev, M.D.

Page 214	Page 216
<p>1 MR. ANDERSON: Objection to form.</p> <p>2 THE DEPONENT: So their conclusion was</p> <p>3 that levels of inflammation -- the way they graded</p> <p>4 it, because they used their own grading system and</p> <p>5 they graded only one part of the inflammation, was</p> <p>6 higher in those meshes which were excised for</p> <p>7 voiding dysfunction rather than for pain and or</p> <p>8 exposure. So they would combine meshes which were</p> <p>9 excised either for pain or for exposure. They did</p> <p>10 not select specifically a group for pain. It was</p> <p>11 a combined group.</p> <p>12 BY MR. HUTCHINSON:</p> <p>13 Q. Move to strike as nonresponsive.</p> <p>14 Dr. Iakovlev, the conclusion of the Hill</p> <p>15 study was that mesh taken out for non-pain reasons</p> <p>16 has more inflammation than mesh taken out because</p> <p>17 of pain. That's what the authors found, right?</p> <p>18 MR. ANDERSON: Objection. Asked and</p> <p>19 answered and you're putting words in the paper's</p> <p>20 mouth. Go ahead.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. Yes or no, Dr. Iakovlev.</p> <p>23 MR. ANDERSON: Same objection.</p> <p>24</p>	<p>1 there.</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. Dr. Iakovlev, are you on page 595?</p> <p>4 A. Yes, I am.</p> <p>5 Q. The author write at the bottom:</p> <p>6 "Vaginally placed, mid-urethral</p> <p>7 sling mesh that is excised for voiding</p> <p>8 dysfunction demonstrates elevated</p> <p>9 levels of inflammation compared to mesh</p> <p>10 that is excised for pain and/or</p> <p>11 exposure."</p> <p>12 Did I read that correctly, sir?</p> <p>13 A. Yes, you did.</p> <p>14 Q. And that's the exact opposite of</p> <p>15 what you found isn't it, sir?</p> <p>16 MR. ANDERSON: Objection.</p> <p>17 THE DEPONENT: No, it is not.</p> <p>18 BY MR. HUTCHINSON:</p> <p>19 Q. Doctor, do you disagree with the</p> <p>20 doctors from the Cleveland Clinic?</p> <p>21 MR. ANDERSON: Objection, form.</p> <p>22 THE DEPONENT: You mean with their</p> <p>23 conclusions? With their results.</p> <p>24</p>
Page 215	Page 217
<p>1 BY MR. HUTCHINSON:</p> <p>2 Q. Can you answer that question yes or</p> <p>3 no?</p> <p>4 MR. ANDERSON: Same objection.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. Can you answer that question yes or</p> <p>7 no?</p> <p>8 MR. ANDERSON: Same objection.</p> <p>9 THE DEPONENT: I cannot agree with your</p> <p>10 wording of the conclusions because the conclusions</p> <p>11 in the paper are somewhat different.</p> <p>12 BY MR. HUTCHINSON:</p> <p>13 Q. Doctor, let's look at the</p> <p>14 conclusions in the paper. Turn with me to page</p> <p>15 595. Are you there?</p> <p>16 A. Well, I'm also looking at</p> <p>17 conclusions in the abstract because it says --</p> <p>18 Q. Move to strike as nonresponsive.</p> <p>19 MR. ANDERSON: You said look at the</p> <p>20 conclusions. There is no conclusions on the page</p> <p>21 you are looking at.</p> <p>22 MR. HUTCHINSON: No, my question was</p> <p>23 turn to page 595. Are you there?</p> <p>24 MR. ANDERSON: There is no conclusion</p>	<p>1 BY MR. HUTCHINSON:</p> <p>2 Q. Yes, sir, you disagree with the</p> <p>3 Cleveland Clinic doctors' conclusions don't you,</p> <p>4 sir?</p> <p>5 A. Well, I mean, the way they did the</p> <p>6 study that's what numbers they got. But if you</p> <p>7 want me to discuss exactly how it was done and how</p> <p>8 they reached to those conclusions I can go ahead</p> <p>9 and discuss it.</p> <p>10 Q. Move to strike as nonresponsive.</p> <p>11 Doctor, my question is do you disagree</p> <p>12 with the conclusions that the Cleveland Clinic</p> <p>13 doctors found in the Hill paper? Yes or no?</p> <p>14 MR. ANDERSON: Objection, asked and</p> <p>15 answered.</p> <p>16 BY MR. HUTCHINSON:</p> <p>17 Q. I'm asking for a yes or no answer.</p> <p>18 Can you answer that question yes or no,</p> <p>19 Dr. Iakovlev?</p> <p>20 MR. ANDERSON: Same objection.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. Not without looking to at your</p> <p>23 transcript. I'm going to object to the extent the</p> <p>24 witness is reviewing an iPad that has in</p>

55 (Pages 214 to 217)



Vladimir Iakovlev, M.D.

Page 218	Page 220
<p>1 real-time his transcript.</p> <p>2 MR. ANDERSON: You can ask every time</p> <p>3 that you would like to know -- you can ask the</p> <p>4 court reporter to repeat it and then she can</p> <p>5 repeat his question for you if you want, or you</p> <p>6 can ask him to repeat it. And when the time is up</p> <p>7 today the time will be up. So if you want to chew</p> <p>8 up your time go right ahead, pal. So go ahead.</p> <p>9 If you need to ask her to re-read something as</p> <p>10 many times as you want then you feel free to do</p> <p>11 it. Alright? Good.</p> <p>12 THE DEPONENT: Okay.</p> <p>13 BY MR. HUTCHINSON:</p> <p>14 Q. Dr. Iakovlev, can you answer that</p> <p>15 question yes or no?</p> <p>16 A. You have to repeat the question now.</p> <p>17 Q. Do you agree with the conclusions</p> <p>18 that the authors from the Cleveland Clinic found</p> <p>19 in the Hill paper?</p> <p>20 MR. ANDERSON: Same objection. Go</p> <p>21 ahead.</p> <p>22 BY MR. HUTCHINSON:</p> <p>23 Q. Yes or no?</p> <p>24 MR. ANDERSON: Objection to form as</p>	<p>1 Q. And her mesh is made of a material</p> <p>2 known as Prolene?</p> <p>3 A. That's a brand name. Ethicon's</p> <p>4 brand name of polypropylene.</p> <p>5 Q. And you know that Ethicon's Prolene</p> <p>6 material has been used in the body for almost 50</p> <p>7 years?</p> <p>8 A. That's correct.</p> <p>9 Q. And St. Michael's, that's the</p> <p>10 hospital where you work in Canada, is that</p> <p>11 correct?</p> <p>12 A. That's correct.</p> <p>13 Q. And St. Michael's uses Prolene</p> <p>14 sutures don't they, sir?</p> <p>15 A. Yes, they do.</p> <p>16 Q. And the hospital where you work in</p> <p>17 Canada uses Prolene mesh for hernia repair. Isn't</p> <p>18 that correct, sir?</p> <p>19 A. Yes, they do.</p> <p>20 Q. And, Dr. Iakovlev, you have never</p> <p>21 told anybody at the hospital where you work to</p> <p>22 stop using Prolene sutures have you?</p> <p>23 MR. ANDERSON: Objection. Go ahead.</p> <p>24 THE DEPONENT: Not sutures.</p>
Page 219	Page 221
<p>1 well.</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. My question is asking for a yes or</p> <p>4 no, Dr. Iakovlev, and then I'll give you an</p> <p>5 opportunity to give a brief explanation. But my</p> <p>6 question is asking for a yes or no. Do you --</p> <p>7 A. I would have no specific opinion</p> <p>8 regarding their conclusions. That's what their</p> <p>9 conclusions in the study. I wasn't doing the</p> <p>10 study. I can explain you what they did, how they</p> <p>11 came to these conclusions but the conclusions are</p> <p>12 there. I mean, I don't agree or disagree. I</p> <p>13 didn't do the study.</p> <p>14 Q. Can you answer that question yes or</p> <p>15 no?</p> <p>16 A. I cannot answer it yes or no because</p> <p>17 I did not do the study.</p> <p>18 Q. Doctor, let's switch gears for a</p> <p>19 minute and I want to talk about Prolene. Okay?</p> <p>20 A. Yes.</p> <p>21 Q. Now, you were asked by the</p> <p>22 plaintiff's lawyer to look at Ms. Ramirez's</p> <p>23 explanted mesh, is that right?</p> <p>24 A. That's correct.</p>	<p>1 BY MR. HUTCHINSON:</p> <p>2 Q. Doctor, let's talk about</p> <p>3 Ms. Ramirez's explant.</p> <p>4 A. Okay.</p> <p>5 Q. It was taken out in September of</p> <p>6 2010, and I'll represent to you that was the date.</p> <p>7 Does that sound about right?</p> <p>8 A. No, it was taken in March 2015.</p> <p>9 Q. I'm sorry, strike that. It was</p> <p>10 implanted -- strike that.</p> <p>11 Ms. Ramirez's TVT-O was implanted in</p> <p>12 September of 2010?</p> <p>13 A. That's correct.</p> <p>14 Q. And part of it was taken out in</p> <p>15 March of 2015?</p> <p>16 A. That's correct.</p> <p>17 Q. And the mesh that you examined was</p> <p>18 in her body for four and a half, five years, is</p> <p>19 that correct?</p> <p>20 A. Yes.</p> <p>21 Q. And at some point after it was</p> <p>22 removed the mesh samples were divided between the</p> <p>23 plaintiffs and defendants, is that correct?</p> <p>24 A. We divided it with the defendant's</p>

56 (Pages 218 to 221)

Vladimir Iakovlev, M.D.

Page 222	Page 224
<p>1 consultant.</p> <p>2 Q. And you received half and the</p> <p>3 defendants received half, is that right?</p> <p>4 A. That's correct.</p> <p>5 Q. So after it was removed from her</p> <p>6 body it was placed in formalin?</p> <p>7 A. That's correct.</p> <p>8 Q. And that's how you received it?</p> <p>9 A. That's correct.</p> <p>10 Q. And you didn't alter the specimen</p> <p>11 did you, sir?</p> <p>12 A. What do you mean?</p> <p>13 Q. Did you alter the specimen? Did you</p> <p>14 try and take any proteins of the specimen?</p> <p>15 MR. ANDERSON: Different question.</p> <p>16 Object to form anyway.</p> <p>17 THE DEPONENT: I don't exactly</p> <p>18 understand what you're asking.</p> <p>19 BY MR. HUTCHINSON:</p> <p>20 Q. Well let's be precise, Dr. Iakovlev.</p> <p>21 You received the excised mesh with tissue on it in</p> <p>22 a jar of formalin, is that correct?</p> <p>23 A. That's correct.</p> <p>24 Q. And you never saw the mesh before it</p>	<p>1 Q. Thank you. Now let's talk about</p> <p>2 tissue, Dr. Iakovlev. You know that human tissue</p> <p>3 contains proteins?</p> <p>4 A. Yes.</p> <p>5 Q. In fact human tissue is mostly</p> <p>6 proteins isn't it, sir?</p> <p>7 A. Human tissue is mostly water and</p> <p>8 then what is not water is mostly proteins.</p> <p>9 Q. Proteins is a close second, will you</p> <p>10 give me that?</p> <p>11 A. Yes.</p> <p>12 Q. And proteins adsorb to the mesh</p> <p>13 explants don't they, sir?</p> <p>14 MR. ANDERSON: Objection to form.</p> <p>15 BY MR. HUTCHINSON:</p> <p>16 Q. They stick to it?</p> <p>17 A. I'm not sure if we can call it like</p> <p>18 this. Proteins surround the --</p> <p>19 Q. The explant.</p> <p>20 MR. ANDERSON: Let him finish his</p> <p>21 answer.</p> <p>22 THE DEPONENT: The implant. Anything</p> <p>23 goes in the body the fluid with proteins fills all</p> <p>24 the spaces and surrounds all the parts. If it</p>
Page 223	Page 225
<p>1 was placed in this formalin, is that right?</p> <p>2 A. That's correct.</p> <p>3 Q. Now, we've used the word "formalin"</p> <p>4 a lot but I want us to understand that's a</p> <p>5 solution that contains chemicals such as</p> <p>6 formaldehyde, isn't that right?</p> <p>7 A. That's right. I explained it</p> <p>8 earlier what it is and how we use it.</p> <p>9 Q. And formaldehyde that's a chemical</p> <p>10 that's used to embalm people who've died, is that</p> <p>11 right?</p> <p>12 A. Part of it. I mean, embalming fluid</p> <p>13 is a complex fluid. There are many other</p> <p>14 substances in it.</p> <p>15 Q. But the bottom line is formalin</p> <p>16 preserves the tissue so it won't rot or decay?</p> <p>17 A. That's correct. It's been used like</p> <p>18 this for pathology for hundred years.</p> <p>19 Q. And this preservation allows a</p> <p>20 pathologist like yourself to study tissue?</p> <p>21 A. That's correct.</p> <p>22 Q. And you'll agree that after tissue</p> <p>23 has been in formalin it will contract?</p> <p>24 A. To a degree.</p>	<p>1 sticks or doesn't stick that's a different</p> <p>2 question but it surrounds.</p> <p>3 BY MR. HUTCHINSON:</p> <p>4 Q. And human protein coat a medical</p> <p>5 device once it's put in the body. Is that</p> <p>6 correct, sir?</p> <p>7 A. Again, I wouldn't call it "coating"</p> <p>8 or "not coating" they surround it. If they coat</p> <p>9 or not that's -- that depends on the materials.</p> <p>10</p> <p>11 THE COURT REPORTER: Counsel in the call</p> <p>12 has been disconnected. Just to let you know.</p> <p>13 THE VIDEOGRAPHER: Going off the record</p> <p>14 at 2:24 p.m.</p> <p>15 --- Break taken.</p> <p>16 THE VIDEOGRAPHER: Back on the record at</p> <p>17 2:27 p.m.</p> <p>18 BY MR. HUTCHINSON:</p> <p>19 Q. Dr. Iakovlev, you'll agree that</p> <p>20 foreign objects such as a mesh implant become</p> <p>21 coated with human proteins?</p> <p>22 A. As I said, coating, not coating,</p> <p>23 permanent coating, I mean, it depends on the</p> <p>24 material, it depends on the timing. At one point</p>

57 (Pages 222 to 225)

Vladimir Iakovlev, M.D.

Page 226	Page 228
<p>1 they can be and then that coating is being 2 resorbed.</p> <p>3 Q. Move to strike as nonresponsive.</p> <p>4 Dr. Iakovlev, my question is for a yes 5 or no, do you agree that foreign objects become 6 coated with human proteins?</p> <p>7 MR. ANDERSON: Same objection. And -- 8 well object to form, and asked and answered, and 9 you can give him the same answer.</p> <p>10 THE DEPONENT: Foreign objects are 11 surrounded. Some of them can be coated, depends 12 on the object, depends on the surface properties.</p> <p>13 BY MR. HUTCHINSON:</p> <p>14 Q. Well in fact, Doctor, you've written 15 "Foreign objects become coated with human proteins 16 before the appearance of the inflammatory cells." 17 That's something you've written.</p> <p>18 A. Yes, I did. And I'm saying that 19 some of them become firmly coated, some of them 20 just surround it. It all depends on an object.</p> <p>21 Q. And, Dr. Iakovlev, you've made no 22 efforts to clean off the proteins from 23 Ms. Ramirez's explant, is that correct?</p> <p>24 MR. ANDERSON: Objection to form.</p>	<p>1 any time?</p> <p>2 Q. At the time it was taken out of her 3 body.</p> <p>4 A. Whatever was outside of the mesh was 5 containing proteins. I mean, that's the nature of 6 human tissues. If it surrounds foreign body there 7 are proteins.</p> <p>8 Q. Thank you. And, Doctor, you 9 understand that formalin crosslinks with proteins 10 that are in the tissue. That's something you 11 understand, is that right?</p> <p>12 A. That's how it preserves it.</p> <p>13 Q. And that's pathology 101 isn't it?</p> <p>14 A. 101 I don't know but how it 15 preserves proteins.</p> <p>16 Q. That's part of the basic 17 pathological training that you've participated in. 18 Is that right, sir?</p> <p>19 A. Yes.</p> <p>20 Q. And you'll agree that the formalin 21 and protein crosslinking will stiffen the tissue?</p> <p>22 A. Yes, it is. It does.</p> <p>23 Q. And it stiffens the tissue so that a 24 pathologist like yourself can make slices of the</p>
Page 227	Page 229
<p>1 THE DEPONENT: That would destroy my 2 histology completely. That's not what 3 pathologists do. Pathologists try to preserve the 4 specimen the way it is and then examine it in 5 cross-sections. I mean, why would I do that?</p> <p>6 BY MR. HUTCHINSON:</p> <p>7 Q. Move to strike as nonresponsive.</p> <p>8 My question, Doctor, you didn't make any 9 efforts to clean the formalin -- strike that.</p> <p>10 My question, Doctor, you didn't make any 11 efforts to clean off the proteins from the explant 12 from Ms. Ramirez, correct?</p> <p>13 MR. ANDERSON: Objection, asked and 14 answered. Go ahead.</p> <p>15 THE DEPONENT: I mean, in opposite. I 16 try to preserve as much as possible of the 17 specimen.</p> <p>18 BY MR. HUTCHINSON:</p> <p>19 Q. Now, we know that the mesh was put 20 in formalin?</p> <p>21 A. That's correct, for preservation.</p> <p>22 Q. For preservation. And we know the 23 mesh was coated with proteins, correct?</p> <p>24 A. At the time of explantation or at</p>	<p>1 bread that you discussed this morning in your 2 direct exam, correct?</p> <p>3 A. No, that's not correct. That's not 4 why we do it. If you want me to give full answer 5 or yes or no answer, I mean, but your statement 6 was not correct.</p> <p>7 Q. Doctor, you don't know the specific 8 details of the chemical reaction that occurs when 9 formalin crosslinks with tissue, you?</p> <p>10 A. Well you just said it, it 11 crosslinks.</p> <p>12 Q. My question, Doctor, is you don't 13 know the specific details of the chemical reaction 14 that occurs when formalin crosslinks with tissues, 15 yes or no?</p> <p>16 A. You just named it. Molecules of 17 formalin crosslink with proteins. That's what the 18 chemical process is.</p> <p>19 Q. That's something that you know?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. Doctor, I want to hand you 22 the trial transcript in the Bellew case. Now you 23 testified under oath in front of a judge and a 24 jury in the Bellew case in West Virginia didn't</p>

58 (Pages 226 to 229)

Vladimir Iakovlev, M.D.

Page 230	Page 232
<p>1 you, sir?</p> <p>2 A. Yes.</p> <p>3 Q. And did you promise to tell the</p> <p>4 truth when you took the witness stand?</p> <p>5 MR. ANDERSON: He testified under oath.</p> <p>6 Why do you keep trying to beat him up like that?</p> <p>7 BY MR. HUTCHINSON:</p> <p>8 Q. Dr. Iakovlev --</p> <p>9 MR. ANDERSON: He testified under oath.</p> <p>10 So stipulated.</p> <p>11 BY MR. HUTCHINSON:</p> <p>12 Q. Dr. Iakovlev, did you promise to</p> <p>13 tell the truth when you were in West Virginia</p> <p>14 talking to the judge and jury?</p> <p>15 MR. ANDERSON: Same objection.</p> <p>16 BY MR. HUTCHINSON:</p> <p>17 Q. Dr. Iakovlev, did you promise to</p> <p>18 tell the truth when you were talking to the judge</p> <p>19 and jury in West Virginia?</p> <p>20 MR. ANDERSON: Same objection.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. I need an answer. Yes or no?</p> <p>23 A. I've answered the question many</p> <p>24 times.</p>	<p>1 bacteria."</p> <p>2 Did I read that correctly, sir?</p> <p>3 MR. ANDERSON: Exactly. Objection to</p> <p>4 improper impeachment. That's exactly what he</p> <p>5 said. Did he read it right?</p> <p>6 THE DEPONENT: Yes, he read it right.</p> <p>7 BY MR. HUTCHINSON:</p> <p>8 Q. And, Doctor, specifically for</p> <p>9 Prolene you don't know the extent to which protein</p> <p>10 forms a bond with Prolene do you?</p> <p>11 A. Um, can you repeat that question?</p> <p>12 Q. You don't know the extent to which</p> <p>13 proteins form a bond with Prolene do you?</p> <p>14 A. Which protein? You have to -- I</p> <p>15 mean, there are hundreds of proteins in the human</p> <p>16 body. Some of them don't bind to anything and</p> <p>17 some of them bind -- I mean their function is to</p> <p>18 bind to surfaces. So which exactly protein are</p> <p>19 you asking?</p> <p>20 Q. Doctor, I'm talking about any of the</p> <p>21 proteins that you've ever studied as a</p> <p>22 pathologist. You don't know the extent to which</p> <p>23 proteins form a bond with Prolene do you, sir?</p> <p>24 A. Like chemical bond?</p>
Page 231	Page 233
<p>1 Q. My question is, Doctor, did you</p> <p>2 promise to tell the truth when you were talking to</p> <p>3 the judge and jury in West Virginia?</p> <p>4 MR. ANDERSON: Same objection.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. Yes or no.</p> <p>7 MR. ANDERSON: Same objection.</p> <p>8 THE DEPONENT: Yes, I did.</p> <p>9 BY MR. HUTCHINSON:</p> <p>10 Q. Doctor, let's look at page 676, line</p> <p>11 24. Question, are you there with me?</p> <p>12 Dr. Iakovlev?</p> <p>13 A. Just let me read the whole page.</p> <p>14 Q. I'm on page 676, line 24. Are you</p> <p>15 there with me now, Dr. Iakovlev?</p> <p>16 A. Yes, I am.</p> <p>17 Q. "QUESTION: Can you tell the jury</p> <p>18 the chemical reaction that occurs when</p> <p>19 formalin crosslinks with the tissues.</p> <p>20 "ANSWER: Specific details?</p> <p>21 "QUESTION: Yes.</p> <p>22 "ANSWER: I don't know specific</p> <p>23 details. It crosslinks, binds proteins</p> <p>24 together so they cannot be degraded by</p>	<p>1 MR. ANDERSON: He asked you a question.</p> <p>2 THE DEPONENT: Are you asking about</p> <p>3 chemical bond?</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. Yes, sir.</p> <p>6 A. Hydrostatic bond, electrostatic</p> <p>7 bond.</p> <p>8 Q. Chemical bond.</p> <p>9 A. I don't think there is any chemical</p> <p>10 bond between proteins and Prolene.</p> <p>11 Q. And, Doctor, you don't know the</p> <p>12 extent to which proteins form a bond with Prolene</p> <p>13 from an adhesion standpoint do you, sir?</p> <p>14 A. What do you mean again adhesion? Is</p> <p>15 it covalent bond? Is it electrostatic,</p> <p>16 hydrostatic bond? I mean, you have to ask</p> <p>17 specific question.</p> <p>18 Q. Can you answer the question as I've</p> <p>19 asked it?</p> <p>20 A. Not the way you asked.</p> <p>21 Q. And, Doctor, let's talk about how</p> <p>22 you prepared the samples from Ms. Ramirez. Okay?</p> <p>23 A. Sure.</p> <p>24 Q. I want to talk about how you made</p>

Vladimir Iakovlev, M.D.

Page 234	Page 236
<p>1 the slices of the bread, so to speak. Alright?</p> <p>2 A. If you want to use that analogy,</p> <p>3 yes, we can.</p> <p>4 Q. And the Ramirez slides were</p> <p>5 processed the same way that you've processed</p> <p>6 slides for other litigation, is that correct?</p> <p>7 A. For all specimens processed in the</p> <p>8 lab, all labs in North America use exactly the</p> <p>9 same process.</p> <p>10 Q. Okay.</p> <p>11 A. And we use the same machinery. We</p> <p>12 use the same chemicals. Everything is processed</p> <p>13 the same way.</p> <p>14 Q. Let's talk about how it was done</p> <p>15 here in Canada, okay?</p> <p>16 A. It's not just in Canada. It's done</p> <p>17 the same way anywhere in the world.</p> <p>18 Q. I understand. It was done pursuant</p> <p>19 to the St. Michael's protocol, is that right?</p> <p>20 A. I'm telling you this is not our</p> <p>21 protocol. It's a machine which is made maybe in</p> <p>22 United States, maybe in Europe and chemicals are</p> <p>23 likely made in the United States. They are bought</p> <p>24 in large supplying companies. Everything is</p>	<p>1 correct? It's a yes or no.</p> <p>2 MR. ANDERSON: Do you understand the</p> <p>3 question.</p> <p>4 THE DEPONENT: I do.</p> <p>5 MR. ANDERSON: Okay. Objection to form.</p> <p>6 Go ahead.</p> <p>7 BY MR. HUTCHINSON:</p> <p>8 Q. I'm asking for a yes or no,</p> <p>9 Dr. Iakovlev.</p> <p>10 A. Yes, they were done exactly the same</p> <p>11 way as all other diagnostic specimens.</p> <p>12 Q. Thank you. Now, as part of the St.</p> <p>13 Michael's protocol the sample was first exposed to</p> <p>14 alcohol or ethanol, correct?</p> <p>15 A. No. The samples came in formalin so</p> <p>16 first stage is formalin.</p> <p>17 Q. And then after formalin, according</p> <p>18 to the St. Michael's protocol, the samples are</p> <p>19 exposed to ethanol or a form of alcohol, correct?</p> <p>20 A. According to all protocols in North</p> <p>21 American laboratories after formalin there are</p> <p>22 several solutions of alcohol.</p> <p>23 Q. Is that a yes, Dr. Iakovlev?</p> <p>24 A. Yes to what?</p>
Page 235	Page 237
<p>1 shared.</p> <p>2 Q. Move to strike as nonresponsive.</p> <p>3 MR. ANDERSON: You said let's talk about</p> <p>4 how it's not in Canada and he's answering your</p> <p>5 question.</p> <p>6 BY MR. HUTCHINSON:</p> <p>7 Q. My question is very specific. It</p> <p>8 was done pursuant to the St. Michael's protocol,</p> <p>9 correct?</p> <p>10 MR. ANDERSON: Objection to the form.</p> <p>11 THE DEPONENT: Our protocols don't</p> <p>12 differ from any other protocol. Again, I don't</p> <p>13 think we can modify much machinery.</p> <p>14 BY MR. HUTCHINSON:</p> <p>15 Q. Move to strike as nonresponsive.</p> <p>16 Dr. Iakovlev, Ms. Ramirez's slides were</p> <p>17 processed pursuant to the St. Michael's protocol,</p> <p>18 correct?</p> <p>19 A. We do exactly the same way as any</p> <p>20 other lab in North America. I mean, our protocols</p> <p>21 are exactly the same as in any other lab.</p> <p>22 Q. Move to strike as nonresponsive.</p> <p>23 Dr. Iakovlev, Ms. Ramirez's slides were</p> <p>24 processed pursuant to the St. Michael's protocol,</p>	<p>1 Q. My question of whether or not the</p> <p>2 sample was exposed to alcohol?</p> <p>3 A. They were exposed to alcohol --</p> <p>4 Q. Thank you.</p> <p>5 A. -- like in any other lab.</p> <p>6 Q. Thank you. And alcohol causes</p> <p>7 tissue to shrink doesn't it, sir?</p> <p>8 MR. ANDERSON: Objection to form.</p> <p>9 THE DEPONENT: To a degree.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Thank you. And as part of the St.</p> <p>12 Michael's protocol the sample of Ms. Ramirez was</p> <p>13 treated with a chemical known as xylene. Is that</p> <p>14 correct, sir?</p> <p>15 A. In all labs the next step after</p> <p>16 alcohol will be xylene.</p> <p>17 Q. And xylene is a solvent isn't it,</p> <p>18 sir?</p> <p>19 A. It is.</p> <p>20 Q. Xylene is used to dissolve the</p> <p>21 paraffin wax used in the embedding process. Isn't</p> <p>22 that correct, sir?</p> <p>23 A. That's correct.</p> <p>24 Q. And xylene is a chemical that's not</p>

60 (Pages 234 to 237)



Vladimir Iakovlev, M.D.

Page 238	Page 240
<p>1 found naturally in the body is it?</p> <p>2 A. No.</p> <p>3 Q. And in fact you've never analyzed</p> <p>4 the chemical effect that xylene has on Prolene</p> <p>5 have you, sir?</p> <p>6 A. I have. I did.</p> <p>7 Q. Doctor, let's look at the Bellew</p> <p>8 transcript. You have it in front of you.</p> <p>9 A. Yes, I do.</p> <p>10 Q. This is when you testified in front</p> <p>11 of the judge and the jury in West Virginia, is</p> <p>12 that correct?</p> <p>13 A. Yes.</p> <p>14 Q. And if you turn with me to page 679.</p> <p>15 A. Yes.</p> <p>16 Q. Line 15.</p> <p>17 A. Yes.</p> <p>18 Q. You say -- or, I'm sorry:</p> <p>19 "QUESTION: You've never analyzed the</p> <p>20 extent that xylene can act as a solvent</p> <p>21 on polypropylene, correct?</p> <p>22 "ANSWER: I did.</p> <p>23 "QUESTION: You -- you --</p> <p>24 "ANSWER: I did place new mesh in</p>	<p>1 for these two concepts is used in completely</p> <p>2 different terms. One is chemical testing the</p> <p>3 other one is chemical changes.</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. Dr. Iakovlev, you've never done any</p> <p>6 chemical testing on the effect that xylene has on</p> <p>7 Prolene have you, sir?</p> <p>8 A. Um, well I used chemicals to stain</p> <p>9 the mesh which had been exposed to xylene, that's</p> <p>10 a part of chemicals. If we talk about some</p> <p>11 chemical reactions, some material scientists type</p> <p>12 of protocols I did not use those.</p> <p>13 Q. Thank you.</p> <p>14 Doctor, I want to hand you what we'll</p> <p>15 mark as Exhibit 8 to your deposition.</p> <p>16 ---DEFENSE EXHIBIT NO. 8: Document</p> <p>17 titled "TR-19/2007 Chemical Resistance</p> <p>18 of Thermoplastics Piping Materials"</p> <p>19 from the Plastics-Pipe Institute, dated</p> <p>20 September 2007.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. This is a Chemical Resistance of</p> <p>23 Thermoplastics Piping Materials document. Do you</p> <p>24 see that?</p>
Page 239	Page 241
<p>1 xylene. It's been sitting for eight</p> <p>2 months. The mesh didn't change.</p> <p>3 "QUESTION: Have you analyzed that mesh</p> <p>4 chemically?</p> <p>5 "ANSWER: No, not chemically."</p> <p>6 Correct?</p> <p>7 A. That's correct.</p> <p>8 Q. So let's be clear, you have never</p> <p>9 analyzed the chemical effect that xylene has on</p> <p>10 Prolene have you, sir?</p> <p>11 A. There is a big difference chemical</p> <p>12 effect versus chemical testing. Because chemical</p> <p>13 effect is changing of chemical structure it can</p> <p>14 manifest itself in different shapes and forms.</p> <p>15 Chemical testing is a specific type of testing and</p> <p>16 it may or may not be specifically related to</p> <p>17 chemical changes.</p> <p>18 Q. Dr. Iakovlev --</p> <p>19 MR. ANDERSON: No, no, hold on. He's</p> <p>20 not --</p> <p>21 MR. HUTCHINSON: Yeah, he is finished.</p> <p>22 MR. ANDERSON: No, his hands are in the</p> <p>23 air and he's not through talking.</p> <p>24 THE DEPONENT: So the word "chemical"</p>	<p>1 A. Doesn't specifically say medical</p> <p>2 devices -- Chemical Resistance of Thermoplastics</p> <p>3 Piping Materials.</p> <p>4 Q. And, Doctor, you've seen this</p> <p>5 document before haven't you? You cite it in your</p> <p>6 reports, your Wave 1 reports don't you, sir?</p> <p>7 A. I reviewed a number of testing --</p> <p>8 tables and testing. Could be one of them.</p> <p>9 Q. Thank you. And, Doctor, let's go to</p> <p>10 the tables, the very last page. Are you there</p> <p>11 with me?</p> <p>12 A. No, just give me one second.</p> <p>13 Q. The last page.</p> <p>14 A. No, just give me one second.</p> <p>15 Q. Oh, I'm sorry.</p> <p>16 A. So which page number?</p> <p>17 Q. The last page, Doctor, of the</p> <p>18 document that you have.</p> <p>19 A. Yes.</p> <p>20 Q. And at the top in the top left it</p> <p>21 says "xylene", under chemical. Is that right?</p> <p>22 A. Yes.</p> <p>23 Q. And along the top line it says,</p> <p>24 "PP". Now that stands for polypropylene, is that</p>

61 (Pages 238 to 241)

Vladimir Iakovlev, M.D.

Page 242	Page 244
<p>1 correct?</p> <p>2 A. Most likely, yes.</p> <p>3 Q. And under PP we have an "N", is that</p> <p>4 correct?</p> <p>5 A. Yes.</p> <p>6 Q. And, Doctor, you know that "N"</p> <p>7 stands for plastic type is not resistant? You</p> <p>8 know that, Doctor, don't you?</p> <p>9 A. It's used in different tables</p> <p>10 differently.</p> <p>11 Q. Well, if you turn to page --</p> <p>12 MR. ANDERSON: Hold on, let him finish.</p> <p>13 THE DEPONENT: I would have to see</p> <p>14 exactly what it means, what temperatures.</p> <p>15 BY MR. HUTCHINSON:</p> <p>16 Q. Doctor, let's look at page 7. My</p> <p>17 question is are you on page 7?</p> <p>18 A. Yes, I am on page 7. So I'm trying</p> <p>19 to read what "N" means.</p> <p>20 Q. And "N" on page 7 means plastic type</p> <p>21 is not resistant, correct?</p> <p>22 A. Not resistant, swelling over 8</p> <p>23 percent, weight loss over 5 percent and elongation</p> <p>24 of break decreased by 50 percent.</p>	<p>1 xylene in a document that you cite in some of your</p> <p>2 reports, it has the letter "N" by polypropylene,</p> <p>3 correct? Can you answer that question, yes or no?</p> <p>4 A. I have to read and what it says and</p> <p>5 what it means plastics and maximum operating</p> <p>6 temperature before I answer that question.</p> <p>7 Because the whole table is designed for maximum</p> <p>8 operating temperature.</p> <p>9 Q. Doctor, my question is on the last</p> <p>10 page of this document polypropylene has the letter</p> <p>11 "N" by it doesn't it, sir?</p> <p>12 A. So the whole table is subject to</p> <p>13 knowing what is maximum operating temperature. I</p> <p>14 don't know what maximum operating temperature here</p> <p>15 is therefore that "N" applies to specific</p> <p>16 condition of maximum operating temperature.</p> <p>17 Q. Move to strike as nonresponsive.</p> <p>18 Dr. Iakovlev, would you show the jury</p> <p>19 the chart on the last page? And hold on just a</p> <p>20 minute, I'm going to ask the videographer to zoom</p> <p>21 in on the word "PP" at the top and the letter "N"</p> <p>22 under the word "PP".</p> <p>23 Now my question to you, Dr. Iakovlev, is</p> <p>24 does the word PP or polypropylene have the letter</p>
Page 243	Page 245
<p>1 Q. And, Doctor, on that same page "PP"</p> <p>2 means polypropylene, correct?</p> <p>3 A. That's correct.</p> <p>4 Q. And if we look on the very last</p> <p>5 page, polypropylene has an "N" by it doesn't it?</p> <p>6 A. Plastics at maximum operating</p> <p>7 temperature.</p> <p>8 Q. No, sir, my question is -- show the</p> <p>9 jury the last page.</p> <p>10 A. Wait a second, I need to see all the</p> <p>11 data in the table before I answer this question.</p> <p>12 Q. Well, my question is polypropylene</p> <p>13 has the letter "N" by it doesn't it, sir?</p> <p>14 A. These tables are designed for</p> <p>15 maximum --</p> <p>16 Q. Move to strike as nonresponsive.</p> <p>17 Dr. Iakovlev, focus on my question.</p> <p>18 MR. ANDERSON: Well, don't tell him what</p> <p>19 to do.</p> <p>20 THE DEPONENT: I cannot interpret the</p> <p>21 table unless I read everything which is in this</p> <p>22 table and I have to know exactly what it means.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. My question, sir, is yes or no, by</p>	<p>1 "N" by it, yes or no.</p> <p>2 MR. ANDERSON: Keep your voice down,</p> <p>3 counsel.</p> <p>4 THE DEPONENT: So the whole table --</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. Move to strike as nonresponsive. I</p> <p>7 need a yes or no.</p> <p>8 MR. ANDERSON: He didn't even answer</p> <p>9 before you moved to strike as nonresponsive at the</p> <p>10 end of your own question. What do you want him to</p> <p>11 answer?</p> <p>12 BY MR. HUTCHINSON:</p> <p>13 Q. Yes or no? Can you answer the</p> <p>14 question yes or no, Dr. Iakovlev?</p> <p>15 A. I cannot answer you yes or no. I</p> <p>16 can only answer you with full answer.</p> <p>17 Q. Dr. Iakovlev, PP has the letter "N"</p> <p>18 by it, yes or no?</p> <p>19 A. Yes.</p> <p>20 Q. And, Dr. Iakovlev, "N" stands for</p> <p>21 plastic type is not resistant, is that correct?</p> <p>22 A. Not resistant at maximum operating</p> <p>23 temperature.</p> <p>24 Q. And, Dr. Iakovlev, this document</p>

62 (Pages 242 to 245)

Vladimir Iakovlev, M.D.

Page 246	Page 248
<p>1 shows that xylene, the chemical that was used with</p> <p>2 Ms. Ramirez's explanted mesh is not resistant to</p> <p>3 xylene doesn't it, sir?</p> <p>4 A. I do not know what maximum operating</p> <p>5 temperature was used for this table, therefore we</p> <p>6 cannot compare two conditions which may be</p> <p>7 completely different. Something may be so hot</p> <p>8 that it starts dissolving.</p> <p>9 Q. You can't answer the question can</p> <p>10 you?</p> <p>11 A. I cannot answer because I don't have</p> <p>12 all information.</p> <p>13 MR. ANDERSON: Objection asked and</p> <p>14 answered.</p> <p>15 BY MR. HUTCHINSON:</p> <p>16 Q. And, Dr. Iakovlev, did you ever</p> <p>17 study the effect that xylene had on Ms. Ramirez's</p> <p>18 explanted mesh?</p> <p>19 A. Well, I saw the specimen which was</p> <p>20 exposed to xylene. I did not see it dissolving.</p> <p>21 Polypropylene was still there, it did not</p> <p>22 dissolve.</p> <p>23 Q. Dr. Iakovlev, the sample was also</p> <p>24 treated with permount wasn't it?</p>	<p>1 Q. Page 683, line 2. Are you there?</p> <p>2 MR. ANDERSON: Objection, inappropriate</p> <p>3 impeachment. It's the exact same question you</p> <p>4 gave and the exact same answer he gave.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. Dr. Iakovlev, are you there with me?</p> <p>7 A. Yes, I am.</p> <p>8 MR. FREESE: Same objection.</p> <p>9 BY MR. HUTCHINSON:</p> <p>10 Q. "QUESTION: And toluene is -- does</p> <p>11 Not behave well with polypropylene. Do</p> <p>12 you know that?</p> <p>13 "ANSWER: I don't know. As I said, I</p> <p>14 put one mesh in xylene and it stays</p> <p>15 intact for several months.</p> <p>16 "QUESTION: But you have not analyzed</p> <p>17 that chemically have you?</p> <p>18 "ANSWER: No, I didn't."</p> <p>19 Did I read that correctly?</p> <p>20 MR. ANDERSON: Different question and</p> <p>21 answer than counsel posed before. It's an</p> <p>22 inappropriate way to impeach someone with their</p> <p>23 testimony, reading different questions and</p> <p>24 different answers. Go ahead.</p>
Page 247	Page 249
<p>1 A. Yes.</p> <p>2 Q. And permount has toluene in it</p> <p>3 doesn't it, sir?</p> <p>4 A. Yes, it's a similar solvent.</p> <p>5 Q. And you've never analyzed the</p> <p>6 chemical effect that toluene has on Prolene have</p> <p>7 you, sir?</p> <p>8 A. Well, you saw it in the pictures.</p> <p>9 The polypropylene was still there, it did not</p> <p>10 dissolve so that is my analysis.</p> <p>11 Q. Move to strike as nonresponsive.</p> <p>12 A. I answered you. I did study the</p> <p>13 slides in permount. These slides they still have</p> <p>14 permount and I showed it in microscope.</p> <p>15 Polypropylene is still there, it did not dissolve.</p> <p>16 Q. Dr. Iakovlev, turn with me to page</p> <p>17 683.</p> <p>18 A. Of?</p> <p>19 Q. Of your transcript for the Bellew</p> <p>20 case. Again that's the same case where you</p> <p>21 testified in front of the judge and jury in West</p> <p>22 Virginia, is that correct?</p> <p>23 A. Yes, it is correct. Which page</p> <p>24 number?</p>	<p>1 THE DEPONENT: There is toluene and then</p> <p>2 xylene. I'm not sure exactly what we were talking</p> <p>3 about.</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. Did I read that correctly, sir?</p> <p>6 A. Oh, you read it correctly.</p> <p>7 Q. Thank you. And, Doctor, when we</p> <p>8 talk about these slides from Ms. Ramirez, they</p> <p>9 were prepared here in your lab, is that right?</p> <p>10 A. That's correct.</p> <p>11 Q. At St. Michael's in Canada, is that</p> <p>12 correct?</p> <p>13 A. Yes.</p> <p>14 Q. And by technicians who work for you,</p> <p>15 is that right?</p> <p>16 A. Not for me for the hospital, for the</p> <p>17 lab.</p> <p>18 Q. And, Doctor, you can't tell us the</p> <p>19 names of any specific technicians who prepared</p> <p>20 those slides for Ms. Ramirez can you?</p> <p>21 MR. ANDERSON: Objection.</p> <p>22 THE DEPONENT: Well, I mean, I know</p> <p>23 their names. I don't exactly who was working on</p> <p>24 that day.</p>

63 (Pages 246 to 249)

Vladimir Iakovlev, M.D.

Page 250	Page 252
<p>1 BY MR. HUTCHINSON:</p> <p>2 Q. Be you can't tell us the specific</p> <p>3 technicians who prepared the slides for</p> <p>4 Ms. Ramirez can you, sir?</p> <p>5 A. No, there were several.</p> <p>6 Q. Doctor, if you will turn with me to</p> <p>7 the exhibit that was used with you this morning,</p> <p>8 Exhibit 7(C). And I'm going to ask the IT folks</p> <p>9 to put it up on to the screen please.</p> <p>10 A. So which?</p> <p>11 Q. Exhibit 7(C).</p> <p>12 A. I don't have the numbers so you have</p> <p>13 to show it to me.</p> <p>14 Q. Do you have that in front of you,</p> <p>15 Doctor?</p> <p>16 A. Yes, I'm just checking where --</p> <p>17 Q. And, Dr. Iakovlev I believe you told</p> <p>18 us this morning that you use this photograph to</p> <p>19 illustrate some degradation, alleged degradation</p> <p>20 of Ms. Ramirez's mesh, is that correct?</p> <p>21 A. That's correct.</p> <p>22 Q. And the pathologists at UT</p> <p>23 Southwestern, that's where Ms. Ramirez went isn't</p> <p>24 it? Strike that.</p>	<p>1 THE DEPONENT: The only person who could</p> <p>2 was the pathologist. He did not examine</p> <p>3 polypropylene for degradation.</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. Thank you. And, Doctor, would you</p> <p>6 look at us, please?</p> <p>7 A. Yes.</p> <p>8 Q. You can't tell the jury what</p> <p>9 triggers the degradation process to occur can you?</p> <p>10 Dr. Iakovlev?</p> <p>11 A. Give me one second. I'm thinking</p> <p>12 how to answer.</p> <p>13 Q. I'm asking for a yes or no.</p> <p>14 MR. ANDERSON: Hey, he's trying to</p> <p>15 answer your question. Quit stop jumping in.</p> <p>16 That's rude.</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. I'll withdraw the question.</p> <p>19 MR. ANDERSON: Alright.</p> <p>20 BY MR. HUTCHINSON:</p> <p>21 Q. Dr. Iakovlev, yes or no, you can't</p> <p>22 tell us what triggers the degradation process to</p> <p>23 occur can you?</p> <p>24 A. It sounds like you're chasing me.</p>
Page 251	Page 253
<p>1 The pathologists where Ms. Ramirez went</p> <p>2 to the hospital they didn't do these same type of</p> <p>3 tests that you did did they?</p> <p>4 A. No, they didn't examine for</p> <p>5 degradation at all.</p> <p>6 Q. In fact not one of the doctors in</p> <p>7 Texas who looked at Ms. Ramirez examined the mesh</p> <p>8 for degradation did they?</p> <p>9 A. Well, I mean the only person who</p> <p>10 could it was a pathologist.</p> <p>11 Q. And, Dr. Iakovlev, that's the same</p> <p>12 pathologist who found no degradation in his final</p> <p>13 pathology report, correct?</p> <p>14 MR. ANDERSON: Objection.</p> <p>15 THE DEPONENT: That's not correct. Who</p> <p>16 did not look for degradation either it's there or</p> <p>17 not.</p> <p>18 BY MR. HUTCHINSON:</p> <p>19 Q. And, Doctor, let's be clear, but we</p> <p>20 look at this exhibit that's shown the jury now,</p> <p>21 not one of the doctors in Texas did this type of</p> <p>22 work did they?</p> <p>23 MR. ANDERSON: Same -- asked and</p> <p>24 answered. Go ahead.</p>	<p>1 Q. Move to strike as non-responsive.</p> <p>2 A. So my answer will be that body</p> <p>3 reaction against polypropylene triggers</p> <p>4 degradation.</p> <p>5 Q. Doctor, you can tell us what</p> <p>6 triggers the degradation process to occur? Is</p> <p>7 that what you're telling us?</p> <p>8 MR. ANDERSON: Objection, different</p> <p>9 question. Go ahead.</p> <p>10 THE DEPONENT: I don't understand the</p> <p>11 question. What specific chemicals? What in</p> <p>12 general process triggers degradation? In general</p> <p>13 the process is triggered by the body reaction</p> <p>14 against polypropylene. Specific chemical</p> <p>15 reactions would be area of expertise of material</p> <p>16 scientists.</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. And, Doctor, you can't tell us what</p> <p>19 triggers the degradation process to occur can you?</p> <p>20 Yes or no?</p> <p>21 MR. ANDERSON: Wait, how many times are</p> <p>22 you going to ask him the same question?</p> <p>23 MR. HUTCHINSON: I haven't gotten an</p> <p>24 answer yet.</p>

64 (Pages 250 to 253)

Vladimir Iakovlev, M.D.

Page 254	Page 256
<p>1 MR. ANDERSON: Yeah, you did. He said,  2 I don't understand the question. What specific  3 chemicals? In general the process is triggered by  4 the body -- body's reaction against polypropylene.  5 Specific chemical reactions would be an area for  6 the material scientists. That is your answer.  7 BY MR. HUTCHINSON:  8 Q. Dr. Iakovlev, my question is asking  9 for a yes or no. You can't tell us what triggers  10 the degradation process to occur. Yes or no?  11 MR. ANDERSON: Objection, asked and  12 answered. You can't make him say yes or no.  13 THE DEPONENT: I cannot answer yes or no  14 when the question is so broad. I have to specify  15 at least to a degree.  16 BY MR. HUTCHINSON:  17 Q. Dr. Iakovlev, I want to hand you  18 your testimony in the Serrano case versus American  19 Medical Systems. Do you have that in front of  20 you?  21 A. Yes, I do.  22 Q. And, Dr. Iakovlev, if you'll turn  23 with me please to page 310.  24 A. So this is different manufacturer,</p>	<p>1 inappropriate method to try to impeach a witness  2 when they give you the exact same answer. Go  3 ahead, Doctor.  4 BY MR. HUTCHINSON:  5 Q. Dr. Iakovlev --  6 A. Just give me a second. I need to  7 read. You're chasing me again. Okay.  8 Q. Are you with me on page 310, line 3,  9 of your Serrano deposition?  10 A. That's correct.  11 Q. "QUESTION: What is the trigger for  12 That degradation process?  13 "ANSWER: It's very complex. I don't  14 think it's been studied. I could not  15 tell you. I mean, the working now  16 evidence is oxidated environment, but  17 I'm not the expert in that specific  18 biochemistry. I cannot testify to  19 that."  20 MR. ANDERSON: Exactly same. Objection.  21 BY MR. HUTCHINSON:  22 Q. Did I read that correctly,  23 Dr. Iakovlev?  24 A. Yes, you did.</p>
Page 255	Page 257
<p>1 this a different product.  2 Q. Move to strike as nonresponsive.  3 My question was can you turn with us to  4 page 310?  5 A. And it's March 6, 2014.  6 Q. Move to strike as nonresponsive.  7 Dr. Iakovlev --  8 MR. ANDERSON: Hey, he's turning into  9 the deposition to find the page that you're asking  10 him to. Can you quit hammering him with questions  11 while he can look.  12 MR. HUTCHINSON: He's there.  13 MR. ANDERSON: Yes or no, can you answer  14 the question?  15 THE DEPONENT: Which page number.  16 BY MR. HUTCHINSON:  17 Q. Page 310.  18 MR. ANDERSON: I guess he's not, huh?  19 BY MR. HUTCHINSON:  20 Q. Page 310. Are you on page 310?  21 Page 310, line 3. Are you there with me,  22 Dr. Iakovlev?  23 MR. ANDERSON: Again, objection. It's  24 the exact same answer he gave. It's an</p>	<p>1 Q. And, Doctor, you can't tell us the  2 rate at which degradation occurs, can you?  3 A. How would we measure rate?  4 MR. ANDERSON: Object to form. Go  5 ahead.  6 THE DEPONENT: You mean thickening of  7 the bark over period of time? Change of molecular  8 weight or tensile -- I mean, exactly how do we  9 measure the objective parameter for that question?  10 BY MR. HUTCHINSON:  11 Q. Move to strike as nonresponsive?  12 A. But you ask a question which is  13 impossible to answer.  14 Q. Doctor, turn with me please to page  15 311, line 4 of your pre-trial deposition. Are you  16 there?  17 A. Which one?  18 Q. Serrano, same case.  19 A. But that's 2014, way before I did my  20 degradation study.  21 Q. Move to strike as nonresponsive.  22 A. Okay.  23 Q. Doctor, turn with me please to page  24 311, line 4. Are you there?</p>

65 (Pages 254 to 257)



Vladimir Iakovlev, M.D.

Page 258	Page 260
<p>1 A. Yes.</p> <p>2 Q. "QUESTION: So you can't tell me</p> <p>3 the rate by which or at which it</p> <p>4 degrades?</p> <p>5 "ANSWER: No."</p> <p>6 Did I read that correctly, Dr. Iakovlev?</p> <p>7 A. "Which line? You didn't say the</p> <p>8 line, at least I didn't hear it.</p> <p>9 Q. Page 311, line 4 of your pre-trial</p> <p>10 deposition. Do you see that?</p> <p>11 A. I do.</p> <p>12 Q. "QUESTION: So you can't tell me</p> <p>13 the rate by which or at which it</p> <p>14 degrades?</p> <p>15 "ANSWER: No."</p> <p>16 Did I read that correctly, Dr. Iakovlev?</p> <p>17 A. Yes, you read it correctly.</p> <p>18 Q. Thank you. And, Doctor, you can't</p> <p>19 tell the jury how long it would take the mesh to</p> <p>20 completely degrade in the body can you?</p> <p>21 A. Well now 2016, since that deposition</p> <p>22 I conducted several studies for degradation and</p> <p>23 published literature.</p> <p>24 Q. So my --</p>	<p>1 place in 2014. Since that time I conducted</p> <p>2 studies researching polypropylene degradation and</p> <p>3 I published peer-reviewed articles describing my</p> <p>4 findings. And since then I acquired way more</p> <p>5 knowledge therefore we cannot compare what I know</p> <p>6 now and what I knew at that time.</p> <p>7 BY MR. HUTCHINSON:</p> <p>8 Q. Move to strike as nonresponsive.</p> <p>9 Dr. Iakovlev, you can't tell us how long</p> <p>10 it would take for the mesh to completely degrade</p> <p>11 in the body can you, sir?</p> <p>12 A. I cannot.</p> <p>13 Q. Thank you. Dr. Iakovlev, let's look</p> <p>14 back at the photograph that's up there on the</p> <p>15 screen, and that's Exhibit 7(C).</p> <p>16 A. Yes.</p> <p>17 Q. And it's my understanding that you</p> <p>18 believe stain is trapped in the little nano</p> <p>19 cavities. Am I correct on that?</p> <p>20 A. Yes.</p> <p>21 Q. And there are no nano cavities shown</p> <p>22 in any of the photographs that you took, correct?</p> <p>23 A. That's why they're nano because you</p> <p>24 cannot see them. They are the nano scale size.</p>
Page 259	Page 261
<p>1 MR. ANDERSON: Do not interrupt him.</p> <p>2 MR. HUTCHINSON: Absolutely. Move to</p> <p>3 strike as nonresponsive. I'm not asking him about</p> <p>4 the deposition any more. I have a different</p> <p>5 question and you know it, Rich.</p> <p>6 MR. FREESE: Counselor, he's going to</p> <p>7 finish what he started and then you can move to</p> <p>8 strike. Until then he's not going to answer any</p> <p>9 more questions until you let him finish. You</p> <p>10 either withdraw or let him finish. It's you.</p> <p>11 MR. HUTCHINSON: My question --</p> <p>12 MR. FREESE: No, no, you either withdraw</p> <p>13 the question or you let him complete, those are</p> <p>14 your two choices.</p> <p>15 MR. HUTCHINSON: I'm not withdrawing the</p> <p>16 question.</p> <p>17 MR. FREESE: Well then he's going to</p> <p>18 answer it.</p> <p>19 MR. HUTCHINSON: But he's talking about</p> <p>20 a deposition in 2016, a test in 2016. That's not</p> <p>21 the question.</p> <p>22 MR. FREESE: Vladimir, finish answering</p> <p>23 the question.</p> <p>24 THE DEPONENT: So that deposition took</p>	<p>1 That resolution is not enough.</p> <p>2 Q. And you can take down that</p> <p>3 photograph.</p> <p>4 The only way you can see -- let me be</p> <p>5 clear. There are no nano cavities shown in the</p> <p>6 photographs that you took for Jennifer Ramirez,</p> <p>7 correct?</p> <p>8 A. I just gave you an answer. They are</p> <p>9 nano. There's -- the resolution of these images</p> <p>10 of this study does not allow. The way we see it</p> <p>11 is because it stains.</p> <p>12 Q. And, Doctor, another way you can see</p> <p>13 nano cavities is by doing transmission electron</p> <p>14 microscopy, correct?</p> <p>15 A. I don't think you can go all the way</p> <p>16 to that resolution. It will definitely give you a</p> <p>17 higher resolution but not all the way to those</p> <p>18 pores where the dye is trapped.</p> <p>19 Q. Dr. Iakovlev, if you'd turn with me</p> <p>20 please to your deposition in the Ramirez case.</p> <p>21 Are you with me?</p> <p>22 A. Yes, I am.</p> <p>23 Q. Page 79, line 23. Are you there</p> <p>24 with me?</p>

66 (Pages 258 to 261)

Vladimir Iakovlev, M.D.

Page 262	Page 264
<p>1 A. Yes.</p> <p>2 Q. "QUESTION: And they are not any</p> <p>3 nano cavities depicted in any of the</p> <p>4 photographs that you've taken?</p> <p>5 "ANSWER: No. The only way I could see</p> <p>6 them, these little cracks, very fine</p> <p>7 cracks, using transmission electron</p> <p>8 microscopy."</p> <p>9 Did I read that correctly, sir?</p> <p>10 A. Yes, you did.</p> <p>11 Q. And, Doctor, you have not done any</p> <p>12 transmission electron microscopy in this case for</p> <p>13 Jennifer Ramirez's have you?</p> <p>14 A. I don't do it for any of the cases.</p> <p>15 Transmission electron microscopy was done for</p> <p>16 research.</p> <p>17 Q. Doctor, when we look at Exhibit C?</p> <p>18 A. Yes.</p> <p>19 Q. And let's bring it back up, Exhibit</p> <p>20 7(C). Doctor, you'll agree that some proteins can</p> <p>21 polarize light won't you, sir?</p> <p>22 A. To a degree.</p> <p>23 Q. Thank you. And, Doctor when we look</p> <p>24 at the bark that's shown in Exhibit 7(C) you've</p>	<p>1 attached to they will not be washed by water.</p> <p>2 Washing by water would be hydrostatic forces so</p> <p>3 not all of them will be washed off.</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. And, Doctor, hematoxylin it's a</p> <p>6 soluble dye isn't it?</p> <p>7 A. Yes, it is.</p> <p>8 Q. And eosin it's a soluble dye isn't</p> <p>9 it?</p> <p>10 A. Yes, but not in water it's in</p> <p>11 alcohol.</p> <p>12 Q. And, Doctor, H&amp;E you talked about</p> <p>13 this in your direct examination that stands for</p> <p>14 hematoxylin and eosin, is that correct?</p> <p>15 A. That's correct.</p> <p>16 Q. And those are the chemicals that</p> <p>17 were used in the staining process on the slides</p> <p>18 that you showed the jury, is that right?</p> <p>19 A. That's correct.</p> <p>20 Q. And if you could pull up for us on</p> <p>21 Exhibit 4(C), I'm sorry yeah, 4(C). Doctor, are</p> <p>22 you there with me?</p> <p>23 A. Which picture? Can you show it to</p> <p>24 me?</p>
Page 263	Page 265
<p>1 never tried to isolate that bark for a chemical</p> <p>2 analysis have you?</p> <p>3 A. No.</p> <p>4 Q. In fact you haven't had an</p> <p>5 analytical chemist confirm that Ms. Ramirez's</p> <p>6 Prolene in fact degraded have you, sir?</p> <p>7 A. I didn't need to. I do my own</p> <p>8 testing.</p> <p>9 Q. And, Doctor, when we talk about</p> <p>10 staining a stain is a soluble dye isn't it?</p> <p>11 A. Most of them are.</p> <p>12 Q. Thank you. And soluble means</p> <p>13 something that dissolves in water like sugar</p> <p>14 dissolves in water, correct?</p> <p>15 A. Not all of them are soluble in water</p> <p>16 some of them need to be dissolved in alcohol. It</p> <p>17 depends on the dye. There are different dyes.</p> <p>18 Some dyes are just extracts from plants.</p> <p>19 Q. Doctor, soluble materials are washed</p> <p>20 away with water aren't they?</p> <p>21 MR. ANDERSON: Objection, asked and</p> <p>22 answered.</p> <p>23 THE DEPONENT: Yes and no. Unless they</p> <p>24 have stronger bond to whatever surface they are</p>	<p>1 Q. Yes, it's the third picture on</p> <p>2 Exhibit 4. Right there.</p> <p>3 A. Okay.</p> <p>4 Q. I just want to make sure that you</p> <p>5 and I are looking at the same thing. Are we?</p> <p>6 A. Yes.</p> <p>7 Q. Doctor, the chemical hematoxylin</p> <p>8 stains blue or purple, right?</p> <p>9 A. Yes.</p> <p>10 Q. And eosin stains pink?</p> <p>11 A. That's correct.</p> <p>12 Q. And, Doctor, you understand that the</p> <p>13 staining process used by a pathologist is an ionic</p> <p>14 chemical reaction don't you, sir?</p> <p>15 A. No, not all stains and in some cases</p> <p>16 most of the dyes actually have very complex</p> <p>17 staining mechanisms. They require additional</p> <p>18 molecules, mordants. It's not just ionic.</p> <p>19 Q. Well, hematoxylin is a positively</p> <p>20 charged ion isn't it?</p> <p>21 A. Hematoxylin is being transformed</p> <p>22 during staining and there are different mordants.</p> <p>23 I'm not sure if it always stays the same charge</p> <p>24 and if charge has no -- has any effect during</p>

67 (Pages 262 to 265)

Vladimir Iakovlev, M.D.

Page 266	Page 268
<p>1 staining, because there are different mordants</p> <p>2 like iron and alum mordant so the answer is quite</p> <p>3 complex.</p> <p>4 Q. Doctor, you understand that</p> <p>5 hematoxylin binds with negatively charged</p> <p>6 substances in the body don't you, sir?</p> <p>7 A. I gave you an answer. Most of the</p> <p>8 dyes have very complex binding mechanisms. It's</p> <p>9 not just electrostatic charge.</p> <p>10 Q. And, Doctor, that's how hematoxylin</p> <p>11 produces color isn't it?</p> <p>12 A. That's how all of the dyes produce</p> <p>13 color, through very complex binding mechanisms</p> <p>14 which require not just dye but also other</p> <p>15 molecules, mostly metals.</p> <p>16 Q. Doctor, eosin, we've talked about</p> <p>17 hematoxylin but I want to talk about eosin, the</p> <p>18 other half, alright?</p> <p>19 A. Okay.</p> <p>20 Q. Eosin, it's a negatively charged ion</p> <p>21 isn't it?</p> <p>22 A. Possible.</p> <p>23 Q. And eosin binds with charged</p> <p>24 substances, positively charged substances in the</p>	<p>1 charged and binds with positively</p> <p>2 charged materials in the body, correct?</p> <p>3 "ANSWER: As far as I remember that's</p> <p>4 the mechanism."</p> <p>5 Did I read that correctly, Dr. Iakovlev?</p> <p>6 A. Yes, you did.</p> <p>7 Q. That was a pretty simple answer that</p> <p>8 you gave to that question, right?</p> <p>9 MR. FREESE: Objection to the form of</p> <p>10 the question.</p> <p>11 MR. ANDERSON: Object to the form and</p> <p>12 you didn't read the remaining part of it. And if</p> <p>13 we were sitting in front of a judge he or she</p> <p>14 would make you read the remaining part of it for</p> <p>15 completeness. And you didn't do that did you,</p> <p>16 counsel?</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. Doctor, you can answer the question.</p> <p>19 That was a pretty simple answer that you gave to</p> <p>20 that question wasn't it?</p> <p>21 MR. FREESE: Objection. Argumentative.</p> <p>22 Don't answer it.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. Are you refusing to answer that</p>
Page 267	Page 269
<p>1 body, doesn't it?</p> <p>2 A. Again, the process is not as simple</p> <p>3 as something positively charged with being</p> <p>4 attracted to negatively charged. The process is</p> <p>5 complex and there are other forces involved in</p> <p>6 staining.</p> <p>7 Q. Move to strike as nonresponsive.</p> <p>8 Doctor, my question is, eosin is</p> <p>9 negatively charged and binds with positively</p> <p>10 charged materials in the body, correct?</p> <p>11 A. I gave you an answer several times</p> <p>12 the same answer. You're trying to make it very</p> <p>13 simple but it's not.</p> <p>14 Q. Okay. Well, Doctor, let's turn to</p> <p>15 the Bellew transcript where you testified in West</p> <p>16 Virginia in front of the judge and jury? Do you</p> <p>17 have that in front of you?</p> <p>18 A. Yes.</p> <p>19 Q. And turn with me to page 687. And</p> <p>20 tell me when you're there, Dr. Iakovlev.</p> <p>21 A. Yes, 687.</p> <p>22 Q. And let's look at line 15.</p> <p>23 A. Let me read the whole page.</p> <p>24 Q. "QUESTION: And eosin is negatively</p>	<p>1 question?</p> <p>2 MR. FREESE: I'm instructing him not to</p> <p>3 answer it. You're just arguing with him.</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. And, Doctor, let's look at page 687</p> <p>6 line 18.</p> <p>7 "QUESTION: Do you know the mechanism?</p> <p>8 "ANSWER: I don't remember exactly what</p> <p>9 happens with eosin but I think you're</p> <p>10 right."</p> <p>11 Did I read that correctly, sir?</p> <p>12 A. You read it correctly.</p> <p>13 Q. And, Doctor, when we talk about</p> <p>14 whether or not hematoxylin has a positive or</p> <p>15 negative charge, or eosin has a positive or</p> <p>16 negative charge, all this means is that a material</p> <p>17 will only stain if it chemically bonds with a</p> <p>18 material of an opposite bond, correct?</p> <p>19 A. This is absolutely wrong because I</p> <p>20 explain you several times, the staining mechanisms</p> <p>21 are very complex. You make it sound like plus,</p> <p>22 minus, connect and nothing else. It does not work</p> <p>23 like that. The mechanisms are very complex.</p> <p>24 Polypropylene bark stains with multiple dyes,</p>

68 (Pages 266 to 269)

Vladimir Iakovlev, M.D.

Page 270	Page 272
<p>1 blue, pink, green, purple and electrostatic charge  2 has nothing to do in the staining of polypropylene  3 bark.  4 Q. Move to strike as nonresponsive.  5 MR. ANDERSON: Just because you don't  6 like the answer --  7 BY MR. HUTCHINSON:  8 Q. I'm asking for a yes or no.  9 MR. ANDERSON: And he gave his answer.  10 BY MR. HUTCHINSON:  11 Q. Am I right or wrong, Doctor?  12 MR. ANDERSON: Asked and answered.  13 THE DEPONENT: You were wrong in your  14 question and your statement.  15 BY MR. HUTCHINSON:  16 Q. Doctor, let's talk about Prolene.  17 Prolene is hydrophobic isn't it?  18 A. That's correct.  19 Q. And that means it's not soluble in  20 water, correct?  21 A. That's correct.  22 Q. And Prolene does not dissolve in  23 water. We can agree on that can't we?  24 A. Yes.</p>	<p>1 Q. Move to strike as nonresponsive.  2 My question, Doctor, is you don't know  3 the positive or negative components of oxidized  4 Prolene do you, sir?  5 A. Because it doesn't matter.  6 Q. Move to strike as nonresponsive.  7 I need a yes or no, Doctor. You don't  8 know the positive or negative components of  9 oxidized Prolene do you, sir?  10 MR. ANDERSON: Asked and answered. Go  11 ahead.  12 THE DEPONENT: As I said, it doesn't  13 matter that's why I don't know.  14 BY MR. HUTCHINSON:  15 Q. Move to strike everything before "I  16 don't know".  17 MR. ANDERSON: Well, I object to your  18 attempt to carve out what you like of his answer  19 and what you don't.  20 BY MR. HUTCHINSON:  21 Q. Doctor, let's talk about whether or  22 not degraded Prolene stains okay?  23 A. I thought we were talking about it  24 for the last 15 minutes or so.</p>
Page 271	Page 273
<p>1 Q. And Prolene is nonionic isn't it,  2 sir?  3 A. In any state? Degraded? I'm asking  4 you.  5 Q. Fair enough. Doctor, Prolene before  6 it's put in the body is nonionic isn't it, sir?  7 A. In that state, yes, it is not.  8 Q. And nonionic means it does not have  9 a charge, correct?  10 A. That's correct.  11 Q. Okay. And, Doctor, you don't know  12 the positive or negative components of oxidized  13 Prolene do you, sir?  14 A. But it doesn't matter because it  15 stains with multiple dyes. It's clear, it's one  16 hundred percent clear that electrostatic charge  17 has nothing to do with the staining mechanism  18 because it stains with multiple different dyes.  19 Any dye you apply to histological tissue will  20 stain the bark. I've stained it with different --  21 Ethicon scientists used phloxine, I used  22 trichrome, I use green stains, red stains, I used  23 at least six, seven different dyes. They all  24 stain it.</p>	<p>1 Q. Well, we're going to talk about it a  2 little more specifically as far as the tests  3 you've done. Do you understand that?  4 A. I thought we were talking about  5 that. Okay.  6 Q. And, Doctor, you know what a control  7 for an experiment is don't you?  8 A. Yes.  9 Q. And just so I'm clear, but doctors  10 and scientists in Canada use controls when they do  11 experiments. Is that right, sir?  12 A. When you do experiment yes, when you  13 do --  14 MR. ANDERSON: Object to the form. Go  15 ahead.  16 THE DEPONENT: When you do experiments  17 in research, yes, you need a control. When you do  18 diagnostic work you don't need a control. You  19 don't have a control for each specimen you examine  20 and make a diagnosis.  21 BY MR. HUTCHINSON:  22 Q. And a control it's part of the  23 scientific process, agree?  24 A. Scientific, yes.</p>

69 (Pages 270 to 273)

Vladimir Iakovlev, M.D.

Page 274	Page 276
<p>1 Q. Okay.</p> <p>2 A. Diagnostic, no. There is no such a</p> <p>3 thing as control for each specimen. It depends on</p> <p>4 what you do.</p> <p>5 Q. Doctor, you'll agree that using a</p> <p>6 control is the hallmark of good science wouldn't</p> <p>7 you?</p> <p>8 MR. ANDERSON: Objection. Go ahead.</p> <p>9 THE DEPONENT: I think we're talking</p> <p>10 about different things.</p> <p>11 BY MR. HUTCHINSON:</p> <p>12 Q. Okay.</p> <p>13 A. Science and research is one part,</p> <p>14 one process, diagnostic work, examination of</p> <p>15 routine, every-day specimens is completely</p> <p>16 different process. One part needs controls, the</p> <p>17 other part for the most part does not. It depends</p> <p>18 on what you do.</p> <p>19 Q. Dr. Iakovlev, a control increases</p> <p>20 the reliability of the results, correct?</p> <p>21 MR. ANDERSON: Objection to form.</p> <p>22 THE DEPONENT: In what process? In the</p> <p>23 research or diagnostic work?</p> <p>24</p>	<p>1 sir?</p> <p>2 A. Yes, I did. I see it every time,</p> <p>3 every time I examine mesh specimen oxidized</p> <p>4 Prolene is staining. I see it as oxidized.</p> <p>5 Q. And, Doctor, you would need to</p> <p>6 intentionally stain that Prolene when you're doing</p> <p>7 this control wouldn't you, sir?</p> <p>8 A. Can you repeat?</p> <p>9 MR. ANDERSON: Objection to the form.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. You would need to intentionally</p> <p>12 stain the Prolene -- or I'm sorry. You would need</p> <p>13 to intentionally oxidize the Prolene, correct?</p> <p>14 MR. ANDERSON: Objection to form, and</p> <p>15 objection as unintelligible.</p> <p>16 THE DEPONENT: I don't exactly</p> <p>17 understand. For what? What purpose exactly?</p> <p>18 BY MR. HUTCHINSON:</p> <p>19 Q. Doctor, the only way to prove that</p> <p>20 oxidized Prolene stains is by purposefully</p> <p>21 oxidizing Prolene and seeing how it reacts to H&amp;E</p> <p>22 stain, right?</p> <p>23 A. No, this is wrong. This is not</p> <p>24 correct.</p>
Page 275	Page 277
<p>1 BY MR. HUTCHINSON:</p> <p>2 Q. In any scientific method, correct,</p> <p>3 sir?</p> <p>4 A. But we don't use controls in</p> <p>5 diagnostic work.</p> <p>6 Q. And, Doctor, in this case a control</p> <p>7 would have been oxidized Prolene that stains</p> <p>8 wouldn't it?</p> <p>9 A. But this case was diagnostic work</p> <p>10 where we don't have controls. We rely on our</p> <p>11 knowledge and experience what is normal what is</p> <p>12 not. Where have you seen a pathologist, even in</p> <p>13 their pathology reports, where it says the control</p> <p>14 was such-and-such tissue from a different patient?</p> <p>15 It's not there. We don't function like this.</p> <p>16 Q. Doctor, you haven't conducted a</p> <p>17 controlled experiment to determine whether or not</p> <p>18 oxidized Prolene stains have you, sir?</p> <p>19 A. For Ms. Ramirez? For all other</p> <p>20 diagnostic specimens? Or for research?</p> <p>21 Q. Doctor, my question is as broad as</p> <p>22 it gets. I'm asking for a yes or no. You haven't</p> <p>23 conducted a control experiment to determine</p> <p>24 whether or not oxidized Prolene stains have you,</p>	<p>1 Q. And, Doctor, you were doing an</p> <p>2 experiment to determine if oxidized Prolene stains</p> <p>3 weren't you?</p> <p>4 A. No. I was doing an experiment</p> <p>5 testing if there can be a model which can model</p> <p>6 oxidation in vivo.</p> <p>7 Q. And, Doctor, you haven't finished</p> <p>8 those tests have you?</p> <p>9 A. Yes, but we are talk about something</p> <p>10 completely different for a different purpose.</p> <p>11 Q. Well, Doctor, my question is do you</p> <p>12 have a control for Ms. Ramirez's case that shows</p> <p>13 oxidized Prolene stains, yes or no?</p> <p>14 A. But we are talking about this for 15</p> <p>15 minutes. We do not have controls for each</p> <p>16 diagnostic specimen. It's not how the diagnostic</p> <p>17 work is done. I mean you're asking for something</p> <p>18 which is never done.</p> <p>19 Q. And I'm just asking is the answer</p> <p>20 no?</p> <p>21 A. You're asking about something which</p> <p>22 is never done. There are no controls for</p> <p>23 diagnostic specimens.</p> <p>24 Q. And you were doing a diagnostic</p>

70 (Pages 274 to 277)



Vladimir Iakovlev, M.D.

Page 278	Page 280
<p>1 specimen for Ms. Ramirez, correct?</p> <p>2 A. That's correct.</p> <p>3 MR. FREESE: When you get to a good spot</p> <p>4 let's take a break.</p> <p>5 MR. HUTCHINSON: Rich, probably five</p> <p>6 minutes or do you need earlier?</p> <p>7 MR. FREESE: Five minutes is fine. I'm</p> <p>8 actually worried about our court reporter than</p> <p>9 anyone else.</p> <p>10 MR. HUTCHINSON: Then let's take a</p> <p>11 break.</p> <p>12 THE VIDEOGRAPHER: Going off the record</p> <p>13 at 3:26 p.m.</p> <p>14 --- Break taken.</p> <p>15 THE VIDEOGRAPHER: We're back on the</p> <p>16 record at 3:43 p.m.</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. Dr. Iakovlev, I believe it's your</p> <p>19 testimony that degradation caused Prolene to</p> <p>20 become brittle, is that right?</p> <p>21 A. That's correct.</p> <p>22 Q. And you're not a material scientist?</p> <p>23 A. I'm not.</p> <p>24 Q. You're not a polymer scientist?</p>	<p>1 A. One ways.</p> <p>2 Q. And, Doctor, you've never done an</p> <p>3 FTIR or any other type of forensic spectroscopy on</p> <p>4 Ms. Ramirez's mesh have you?</p> <p>5 A. No.</p> <p>6 Q. And you've never done any molecular</p> <p>7 weight testing on Ms. Ramirez's mesh have you?</p> <p>8 A. No.</p> <p>9 Q. You didn't measure the tensile</p> <p>10 strength?</p> <p>11 A. No.</p> <p>12 Q. You didn't measure the elongation?</p> <p>13 A. No.</p> <p>14 Q. You didn't measure the toughness?</p> <p>15 A. No.</p> <p>16 Q. In fact you didn't do any type of</p> <p>17 bench-top testing to determine whether or not the</p> <p>18 physical properties decreased did you, sir?</p> <p>19 A. What do you mean "bench top"? You</p> <p>20 mean like wet lab experimental testing? I have</p> <p>21 not.</p> <p>22 Q. And, Doctor, in fact you haven't</p> <p>23 done any type of analytical chemistry testing on</p> <p>24 Ms. Ramirez's explant, have you?</p>
Page 279	Page 281
<p>1 A. I'm not.</p> <p>2 Q. You're not an analytical chemist?</p> <p>3 A. I'm not.</p> <p>4 Q. You haven't consulted with anyone in</p> <p>5 those fields about Ms. Ramirez's explant have you,</p> <p>6 sir?</p> <p>7 A. I have not.</p> <p>8 Q. And you would agree that if the</p> <p>9 Prolene was brittle then that would affect the</p> <p>10 physical properties of the mesh?</p> <p>11 A. That's correct.</p> <p>12 Q. And, Doctor, analytical chemists</p> <p>13 they have equipment to analyze materials, don't</p> <p>14 they?</p> <p>15 A. Yes, they do. That's what they do.</p> <p>16 Q. Like FTIR, is that right?</p> <p>17 A. That's correct.</p> <p>18 Q. And FTIR is just a way to determine</p> <p>19 the fingerprint of a chemical. Is that fair to</p> <p>20 say?</p> <p>21 A. It can be used as an analogy.</p> <p>22 Q. And gel permeation chromatography,</p> <p>23 that's a way to determine loss of molecular</p> <p>24 weight, is that correct?</p>	<p>1 A. No.</p> <p>2 Q. Doctor, I assume that your opinion</p> <p>3 is that oxidation is what is causing the</p> <p>4 degradation that you spoke about this morning, is</p> <p>5 that correct?</p> <p>6 A. Well, that's the current knowledge</p> <p>7 and current understanding that oxidation triggers</p> <p>8 degradation.</p> <p>9 Q. And is that your understanding?</p> <p>10 A. That's my understanding.</p> <p>11 Q. Okay. But now doctor, you can't</p> <p>12 testify to a reasonable degree of scientific</p> <p>13 certainty that oxidation is what's causing the</p> <p>14 degradation, can you?</p> <p>15 MR. ANDERSON: Objection to form.</p> <p>16 THE DEPONENT: Well, I can testify that</p> <p>17 the body of the literature indicates that</p> <p>18 oxidation is the most probable mechanism of</p> <p>19 degradation.</p> <p>20 BY MR. HUTCHINSON:</p> <p>21 Q. Move to strike as nonresponsive.</p> <p>22 My question, Doctor, is whether or not</p> <p>23 you can testify to a reasonable degree of</p> <p>24 scientific certainty that the oxidation is what is</p>

71 (Pages 278 to 281)

Vladimir Iakovlev, M.D.

Page 282	Page 284
<p>1 causing degradation?</p> <p>2 A. Yes, that's what I said, to</p> <p>3 reasonable degree of scientific certainty. All</p> <p>4 body of literature indicates that this is most</p> <p>5 probable mechanism of degradation.</p> <p>6 Q. Doctor, when we talk about oxidation</p> <p>7 that's the addition of an oxygen atom through the</p> <p>8 chemical structure, isn't it?</p> <p>9 A. Yes, in part. It may not stay there</p> <p>10 forever but it involves oxygen.</p> <p>11 Q. And you understand that if oxidation</p> <p>12 occurs you must have a loss of molecular weight?</p> <p>13 MR. ANDERSON: Objection.</p> <p>14 THE DEPONENT: I think now we're going</p> <p>15 into an area that is beyond my expertise, into</p> <p>16 chemical analysis.</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. You can't answer that question, is</p> <p>19 that correct?</p> <p>20 A. No, it's not my area of expertise.</p> <p>21 Q. And just so I'm clear, from a</p> <p>22 chemistry standpoint you cannot answer that</p> <p>23 question, is that right?</p> <p>24 MR. ANDERSON: Objection, asked and</p>	<p>1 practice of pathology."</p> <p>2 Q. Thank you. And, Doctor, you're not</p> <p>3 an expert in chemistry as it relates to oxidation</p> <p>4 are you? Dr. Iakovlev?</p> <p>5 A. Well, you ask a very broad question</p> <p>6 and --</p> <p>7 Q. My question is simple. You're not</p> <p>8 on expert in chemistry as it relates to oxidation</p> <p>9 are you, sir?</p> <p>10 A. Oxidation happens all the time.</p> <p>11 Burning a fire is oxidation. I mean, you ask a</p> <p>12 question so broad. Yes, I am an expert in some</p> <p>13 parts of oxidation. I mean, if you ask me what</p> <p>14 happens when something burns, oxidizes fast I can</p> <p>15 tell you. In terms of polymer science, how this</p> <p>16 happens I'm not an expert in that field.</p> <p>17 Q. Doctor, you'll agree that if</p> <p>18 oxidation occurs strong carbonyls -- strike that.</p> <p>19 If oxidation occurs FTIR must show</p> <p>20 strong carbonyl bands, you'll agree with that</p> <p>21 wouldn't you?</p> <p>22 A. I have no opinion regarding that</p> <p>23 because as I told you I'm not a chemical</p> <p>24 scientist.</p>
Page 283	Page 285
<p>1 answer. He just said he can't do, it's outside of</p> <p>2 his field and we're not offering him for chemical</p> <p>3 analysis, or any of those other issues that you're</p> <p>4 going through. You know that's for polymer</p> <p>5 scientists. So he gave you the answer. It's the</p> <p>6 same answer again. We're not offering him for</p> <p>7 that.</p> <p>8 BY MR. HUTCHINSON:</p> <p>9 Q. You can answer, Doctor.</p> <p>10 A. My answer is that I am not a</p> <p>11 chemical scientist. I did not do chemical</p> <p>12 testing.</p> <p>13 Q. Well, Doctor, let's look at your</p> <p>14 expert report on page 1 for Mr. Ramirez. You're</p> <p>15 there, yes, sir?</p> <p>16 A. Yes.</p> <p>17 Q. The last line, "I am knowledgeable</p> <p>18 in the areas of chemistry." Did I read that</p> <p>19 correctly, sir?</p> <p>20 A. Well let's read the full sentence.</p> <p>21 "I am knowledgeable in the areas of</p> <p>22 chemistry, hematology, microbiology,</p> <p>23 serology, immunology and other special</p> <p>24 laboratory studies as they relate to my</p>	<p>1 Q. And, Doctor, if oxidation occurs</p> <p>2 there will be a loss of toughness and tensile</p> <p>3 strength and elongation, correct?</p> <p>4 MR. ANDERSON: Objection. He just said</p> <p>5 that this is outside of his area of specialty.</p> <p>6 Are you just going to keep asking him questions</p> <p>7 and he can just say it every time?</p> <p>8 BY MR. HUTCHINSON:</p> <p>9 Q. Is that outside of your area of</p> <p>10 expertise, Doctor?</p> <p>11 A. That's correct.</p> <p>12 Q. And, Doctor, you're unaware of any</p> <p>13 peer-reviewed literature that shows Prolene has</p> <p>14 loss molecular weight in body, correct?</p> <p>15 A. The same answer. I'm not a chemical</p> <p>16 scientist. I do not focus on that aspect. There</p> <p>17 might be some literature, because it's outside of</p> <p>18 my area of expertise I am not focus on this</p> <p>19 question when I review articles.</p> <p>20 Q. And, Doctor, you're unaware of any</p> <p>21 studies that show Prolene has lost molecular</p> <p>22 weight in the body, correct?</p> <p>23 MR. ANDERSON: Objection, asked and</p> <p>24 answered.</p>

72 (Pages 282 to 285)

Vladimir Iakovlev, M.D.

Page 286	Page 288
<p>1 THE DEPONENT: I just answered the 2 question. Since I am not a chemical scientists 3 when I review this literature I am not focusing on 4 that specific topic. There may or may not be 5 literature out there answering your question. 6 BY MR. HUTCHINSON: 7 Q. Dr. Iakovlev, you can't tell the 8 jury the chemical structure of oxidized Prolene 9 can you? 10 A. The same answer. Do you want me to 11 repeat? 12 MR. ANDERSON: He said same answer. 13 It's outside of his expertise. 14 BY MR. HUTCHINSON: 15 Q. Is that outside of your area of 16 expertise? 17 A. Yes, that's correct. 18 Q. And, Doctor, you're not an expert in 19 the direct oxidation of polypropylene are you? 20 A. No. Well, I can show what happens 21 in the histological sections with degraded 22 polypropylene, but what happens in terms of 23 chemical reactions would be area of expertise for 24 material scientists.</p>	<p>1 "ANSWER: That's correct." 2 Did I read that correctly? 3 A. You have to give me a second to see 4 exactly what questions are asked. 5 MR. ANDERSON: And, again, improper use 6 of impeachment. He said in his answer, "I am not 7 an expert in chemical reactions behind 8 degradation." I don't know what you're trying to 9 get at, counsel. 10 MS. VERBEEK: Can we agree on the 11 record, because I'm cutting in and out, that one 12 objection is good for all? 13 MR. HUTCHINSON: Sure. Absolutely. 14 MS. VERBEEK: Thank you. 15 MR. HUTCHINSON: You're 16 BY MR. HUTCHINSON: 17 Q. Dr. Iakovlev, did I read that 18 correctly? 19 A. Okay. Let's go back to the same -- 20 which page and which line did you read? 21 Q. Doctor, page 689, line 6. 22 "It's fair to say, isn't it, Doctor, 23 that you're not an expert in the direct 24 oxidation of polypropylene?"</p>
Page 287	Page 289
<p>1 Q. So my question is you're not an 2 expert in the direct oxidation of polypropylene. 3 Yes or no? 4 MR. ANDERSON: He just answered it. He 5 doesn't have to give you a yes or no. And in fact 6 he -- 7 MR. HUTCHINSON: I just want to know if 8 he's an expert. 9 MR. ANDERSON: Well, he gave you the 10 answer. 11 BY MR. HUTCHINSON: 12 Q. You can answer, Doctor. 13 A. I'm an expert in terms of how the 14 process of degradation changes properties of 15 polypropylene in histological sections. I am not 16 an expert in chemical reactions behind. 17 Q. Doctor, let's look at what you told 18 the jury in Bellew on page 689. Page 689, line 6. 19 Tell me when you're there. 20 A. Yes. 21 Q. Question, it's the same question I 22 just asked you. 23 "Doctor, you're not an expert in the 24 direct oxidation of polypropylene?"</p>	<p>1 "Answer: That's correct." 2 Did I read that correctly, Dr. Iakovlev? 3 A. Yes, you read it correctly. 4 Q. Thank you. And, Doctor, we talked 5 about this earlier but you know that Prolene is 6 the brand name for Ethicon's mesh, right? 7 A. Yes. 8 Q. And you know that Prolene is made 9 out of polypropylene plus special additives, is 10 that correct? 11 A. That's correct. 12 Q. And in fact that's what makes 13 Prolene different than other meshes on the market. 14 Is that correct, sir? 15 MR. FREESE: Object to the form and the 16 question. 17 THE DEPONENT: I don't think I can 18 answer that question. I don't know if it is 19 different and if that's the only thing which makes 20 it different. 21 BY MR. HUTCHINSON: 22 Q. That's outside of your area of 23 expertise? 24 A. Yes.</p>

73 (Pages 286 to 289)

Vladimir Iakovlev, M.D.

Page 290	Page 292
<p>1 Q. And so you can't tell us the names 2 of antioxidants that Ethicon adds to polypropylene 3 to make Prolene can you, sir? 4 A. No, I cannot. 5 Q. And you can't tell the jury how 6 those antioxidants prevent oxidation can you, sir? 7 A. No, I cannot. I know that they need 8 to be used because it degrades, that's why it's 9 being used. 10 Q. In fact you can't tell the jury the 11 names of the antioxidants that are used can you, 12 sir? 13 MR. ANDERSON: Objection. Asked and 14 answered. Go ahead. 15 THE DEPONENT: I cannot. 16 BY MR. HUTCHINSON: 17 Q. I'm sorry? 18 A. I cannot. 19 Q. Thank you. 20 A. I can tell you that Ethicon needs 21 antioxidants in polypropylene to delay 22 degradation. 23 Q. And, Doctor, you've never done an 24 analysis to determine or quantify the rate at</p>	<p>1 BY MR. ANDERSON: 2 Q. Doctor? 3 MR. ANDERSON: The same objection. 4 BY MR. HUTCHINSON: 5 Q. Did you get that wood from the 6 plaintiff's lawyer? 7 A. This one? This specific? 8 Q. Yes, sir. 9 A. Yes, it was brought by plaintiff's 10 lawyer. 11 Q. And if you'll hold it up right 12 there. Now, you use this piece of wood to 13 demonstrate that there's nothing wrong with the 14 core, is that right? 15 A. Yes. 16 Q. Okay. Now, Dr. Iakovlev, I want to 17 hand you another piece of wood. 18 A. Yes. 19 MR. ANDERSON: Plaintiff's lawyer give 20 you that one. 21 MR. FREESE: We looked at that one 22 yesterday too. 23 BY MR. ANDERSON: 24 Q. Move to strike.</p>
Page 291	Page 293
<p>1 which these antioxidants are depleted have you, 2 sir? 3 MR. ANDERSON: Well he just said he 4 didn't know what they are so how in the world is 5 he going to know if they're depleted? But 6 objection. 7 BY MR. HUTCHINSON: 8 Q. Is that correct, Doctor? Is that 9 correct, sir? 10 A. That's correct. 11 Q. Thank you. And, Doctor, you showed 12 the jury the slice of wood earlier. Do you 13 remember that? 14 A. Yes, I do. 15 Q. And do you still have it with you? 16 A. Yes, I do. 17 Q. And why don't you put it up there on 18 the table? 19 A. Sure. 20 Q. And by the way where did you get it? 21 Where did you get that wood? From the plaintiff's 22 lawyer? 23 MR. ANDERSON: Objection. 24 THE DEPONENT: Um ...</p>	<p>1 Dr. Iakovlev, you have never seen a 2 fiber from a mesh explant have a crack like that 3 have you, sir? 4 A. Which one? Like this? 5 Q. Yes, sir. 6 A. When there is chattering in specific 7 conditions they're in artifact which cracks the 8 fibers. 9 Q. And my question, sir -- why don't 10 you hold the smaller piece up? 11 A. Yes. 12 Q. Just the smaller one, I know the 13 bigger one's heavy. You've never seen a fiber 14 under the microscope that looks like that have 15 you, sir? 16 A. Not artifact. 17 MR. HUTCHINSON: Object to the form of 18 the question. 19 THE DEPONENT: No, I have never seen it. 20 BY MR. HUTCHINSON: 21 Q. Thank you. And, Doctor, by the way 22 that wood, let's look at the exhibit that you used 23 in your direct exam. 24 A. Okay.</p>

74 (Pages 290 to 293)

Vladimir Iakovlev, M.D.

Page 294	Page 296
<p>1 Q. That wood's never been in the body</p> <p>2 has it?</p> <p>3 A. No.</p> <p>4 Q. And if it had been in the body it</p> <p>5 would be covered with proteins wouldn't it, sir?</p> <p>6 MR. ANDERSON: Objection.</p> <p>7 THE DEPONENT: Yes.</p> <p>8 BY MR. ANDERSON:</p> <p>9 Q. And in fact it would be coated,</p> <p>10 using your own words, with proteins wouldn't it,</p> <p>11 sir?</p> <p>12 A. I wouldn't say coated, it would</p> <p>13 probably be soaked into the pores of the bark</p> <p>14 here.</p> <p>15 Q. And, Doctor, you testified this</p> <p>16 morning that eosin stains proteins pink, correct?</p> <p>17 A. Yes.</p> <p>18 Q. And, Doctor, let's look at your</p> <p>19 Exhibit 1, which is Ms. Ramirez's report?</p> <p>20 A. Yes.</p> <p>21 Q. And if you'll turn with me please to</p> <p>22 page 25? And let's look at Exhibit 17(A).</p> <p>23 A. Page 25. Of which report?</p> <p>24 MR. ANDERSON: Of the case-specific</p>	<p>1 MR. HUTCHINSON: Absolutely. Just</p> <p>2 because you say he is doesn't mean he is.</p> <p>3 MR. ANDERSON: Oh God. He's going to</p> <p>4 answer your question the way he's going to answer</p> <p>5 it. You want to move to strike it? Move to</p> <p>6 strike it.</p> <p>7 MR. HUTCHINSON: I'll be happy to.</p> <p>8 MR. ANDERSON: I'm sure you would.</p> <p>9</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Dr. Iakovlev?</p> <p>12 A. Yes.</p> <p>13 Q. You'll agree that the outer layer</p> <p>14 that you're showing the jury is pink. Yes or no?</p> <p>15 Can you answer that question yes or no?</p> <p>16 A. I cannot answer that question yes or</p> <p>17 no. I have to give you a full answer. And the</p> <p>18 full answer will be that the outer portions of the</p> <p>19 bark, the very edge of this is more pink. There</p> <p>20 are more proteins on the surface but when we go</p> <p>21 deeper down the intensity of color drops and it</p> <p>22 becomes more purple.</p> <p>23 Q. Move to strike everything after "I</p> <p>24 cannot answer yes or no".</p>
Page 295	Page 297
<p>1 report or the general report?</p> <p>2 BY MR. ANDERSON:</p> <p>3 Q. Yes, case specific. Page 25, figure</p> <p>4 JR(17)(A).</p> <p>5 A. Yes.</p> <p>6 Q. And, Doctor, why don't you hold that</p> <p>7 up for the jury so they can see it please? And</p> <p>8 Doctor, you testified earlier that eosin stains</p> <p>9 proteins pink. Do you remember that?</p> <p>10 A. Yes.</p> <p>11 Q. And, Doctor, you'll agree that the</p> <p>12 outer layer that in the picture that you've</p> <p>13 labelled JR(17) is pink, correct?</p> <p>14 A. More purple.</p> <p>15 Q. Would you show it to the jury?</p> <p>16 A. The outer part.</p> <p>17 Q. My question, Doctor, is really</p> <p>18 simple.</p> <p>19 MR. ANDERSON: He's trying to answer</p> <p>20 your question.</p> <p>21 MR. HUTCHINSON: No, he's not. My</p> <p>22 question is very simple.</p> <p>23 MR. ANDERSON: Yes he is. Just because</p> <p>24 you say he's not doesn't mean he's not.</p>	<p>1 Dr. Iakovlev, you discussed in your</p> <p>2 direct examination some literature this morning.</p> <p>3 Do you remember that?</p> <p>4 A. Yes, I do.</p> <p>5 Q. And in fact let's look at some of</p> <p>6 that literature. Let's look at Exhibit 20. I'm</p> <p>7 sorry, Exhibit 19.</p> <p>8 A. Just give me a second.</p> <p>9 Q. Pathology of Explanted Transvaginal</p> <p>10 Meshes.</p> <p>11 A. This is Exhibit 20.</p> <p>12 Q. Exhibit 19.</p> <p>13 A. Oh 19. Okay.</p> <p>14 Q. Pathology of Explanted Transvaginal</p> <p>15 Meshes. Do you see that, Doctor?</p> <p>16 A. Yes, I do.</p> <p>17 Q. And this is a publication that you</p> <p>18 authored, correct?</p> <p>19 A. That's correct.</p> <p>20 Q. And it was published in 2014, is</p> <p>21 that right?</p> <p>22 A. That's correct.</p> <p>23 Q. And, Doctor, you were a paid expert</p> <p>24 witness for the plaintiffs at the time of this</p>

75 (Pages 294 to 297)



Vladimir Iakovlev, M.D.

Page 298	Page 300
<p>1 study weren't you? In 2014?</p> <p>2 A. Yes.</p> <p>3 Q. And if we look at that very top</p> <p>4 paragraph in the abstract do you see that?</p> <p>5 A. Yes, I do.</p> <p>6 Q. And if you can pull that up? And I</p> <p>7 want you to read the very first sentence of the</p> <p>8 paper you authored.</p> <p>9 "The use of polypropylene mesh</p> <p>10 devices for pelvic organ prolapse</p> <p>11 spread rapidly during the last decade</p> <p>12 yet our knowledge of the mesh tissue</p> <p>13 interaction is far from complete."</p> <p>14 A. That's correct.</p> <p>15 Q. Did I read that correctly, sir?</p> <p>16 A. You read it correctly.</p> <p>17 Q. Thank you. And let's look at the</p> <p>18 other paper that you authored, it's Exhibit 20.</p> <p>19 A. Yes.</p> <p>20 Q. And it's titled "Degradation of</p> <p>21 polypropylene In Vivo Microscopic Analysis". Do</p> <p>22 you have that paper in front of you, Doctor?</p> <p>23 A. Yes, I do.</p> <p>24 Q. In fact you were a paid expert</p>	<p>1 with the mesh remain incompletely understood."</p> <p>2 Did I read that correctly, sir?</p> <p>3 A. That's correct.</p> <p>4 Q. And in fact you go on to write, for</p> <p>5 example, "The fundamental question as to whether</p> <p>6 or not polypropylene degrades in the body is still</p> <p>7 unresolved." Did I read that correctly?</p> <p>8 A. That's correct.</p> <p>9 Q. And, Doctor, let's look at some more</p> <p>10 literature that you cite.</p> <p>11 A. Sure.</p> <p>12 Q. I would like to turn your attention</p> <p>13 to Exhibit 8 this is the Celine Mary article,</p> <p>14 correct?</p> <p>15 A. Well let me first pull the exhibit.</p> <p>16 Yes.</p> <p>17 Q. And this is one of the documents</p> <p>18 that you relied on in reaching your opinions, is</p> <p>19 that correct, sir?</p> <p>20 A. That's correct.</p> <p>21 Q. And if we look at the first</p> <p>22 paragraph on the first page it says,</p> <p>23 "Polypropylene", and I'll give the --</p> <p>24 "Polypropylene was introduced as a suture material</p>
Page 299	Page 301
<p>1 witness for the plaintiffs at the time of this</p> <p>2 study weren't you?</p> <p>3 A. Yes, I was.</p> <p>4 Q. And, Doctor, this paper was</p> <p>5 published by you in July of 2015, is that correct?</p> <p>6 A. That's correct.</p> <p>7 Q. And in fact that's less than a year</p> <p>8 ago isn't it, sir?</p> <p>9 A. That's correct.</p> <p>10 Q. And let's look at the abstract. And</p> <p>11 on the left-hand side paragraph in the middle it</p> <p>12 says, "The fundamental question", do you see that?</p> <p>13 A. I do.</p> <p>14 Q. And Doctor, you write, "The</p> <p>15 fundamental question as to whether polypropylene</p> <p>16 degrades in the body is still debated." Did I</p> <p>17 read that correctly?</p> <p>18 A. That's correct. That's what we're</p> <p>19 doing right now.</p> <p>20 Q. And in fact, Doctor, let's look at</p> <p>21 the first page. You can pull that down. And the</p> <p>22 last sentence under the paragraph "Introduction".</p> <p>23 Doctor, you write, just less than a year ago, "The</p> <p>24 causes and mechanisms of complications associated</p>	<p>1 in the late 1950s." Did I read that correctly?</p> <p>2 A. Yes.</p> <p>3 Q. "And it has a high flexibility and</p> <p>4 tensile strength and exhibits low thrombogenicity</p> <p>5 and tissue reaction." Did I read that correctly?</p> <p>6 A. Well with little mistake but for the</p> <p>7 most part, yes.</p> <p>8 Q. But I did read the fact that it</p> <p>9 exhibits low tissue reaction correctly didn't I,</p> <p>10 sir? If you can highlight it please.</p> <p>11 "Polypropylene exhibits low thrombogenicity and</p> <p>12 tissue reaction." Did I read that correctly, sir?</p> <p>13 A. Yes, now you've read it correctly.</p> <p>14 Q. Thank you. And let's look at the</p> <p>15 Jogenbloed article, Doctor.</p> <p>16 A. Exhibit number?</p> <p>17 Q. Exhibit 13.</p> <p>18 A. Yes.</p> <p>19 Q. And if we look at the title, that's</p> <p>20 the only thing I want to look at on this document.</p> <p>21 A. Yes.</p> <p>22 Q. It says "Degradation of</p> <p>23 Polypropylene in the Human Eye". Did I read that</p> <p>24 correctly?</p>

76 (Pages 298 to 301)

Vladimir Iakovlev, M.D.

Page 302	Page 304
<p>1 A. Yes. It degrades in the eye, in</p> <p>2 degrades in other tissues.</p> <p>3 Q. And, Doctor, you understand that UV</p> <p>4 light degrades polypropylene don't you?</p> <p>5 A. Yes.</p> <p>6 Q. And, Doctor, vaginal mesh isn't</p> <p>7 exposed to UV light in the pelvic region is it,</p> <p>8 sir?</p> <p>9 A. Not in normal conditions.</p> <p>10 Q. Thank you. Let's look at Exhibit</p> <p>11 15, Doctor, that's the Leibert study.</p> <p>12 A. Yes.</p> <p>13 Q. In fact this is another document</p> <p>14 that you relied on in support of your opinions,</p> <p>15 correct?</p> <p>16 A. Yes.</p> <p>17 Q. And let's look at the very last line</p> <p>18 in the summary on the first page. It says,</p> <p>19 "Long-term effects of polymer implantation upon</p> <p>20 tissue were not studied in this work." Did I read</p> <p>21 that correctly, sir?</p> <p>22 A. That's correct.</p> <p>23 Q. And in fact, Doctor, you understand</p> <p>24 from reading the Leibert article that the</p>	<p>1 A. Yes, at the time when they analyzed</p> <p>2 that.</p> <p>3 Q. Thank you. And if we look at the</p> <p>4 "Conclusions" section?</p> <p>5 A. I do.</p> <p>6 Q. If we leave -- if we read the very</p> <p>7 last line in number 5 it says:</p> <p>8 "These results support the view</p> <p>9 that the changes observed for pure</p> <p>10 implanted filaments are due to</p> <p>11 oxidation rather than diffusional or</p> <p>12 other unknown effects since the</p> <p>13 antioxidant specifically inhibits</p> <p>14 and/or retards oxidation."</p> <p>15 Did I read that correctly, sir?</p> <p>16 A. Yes, you read it correctly.</p> <p>17 Q. Thank you. And let's look at</p> <p>18 Exhibit 18, which was the Wood article.</p> <p>19 A. Yes.</p> <p>20 Q. Dr. Iakovlev, you relied on this for</p> <p>21 your opinions didn't you, sir?</p> <p>22 A. Yes, I did.</p> <p>23 Q. And Dr. Iakovlev, you'll agree that</p> <p>24 the Wood article doesn't even discuss a product</p>
Page 303	Page 305
<p>1 scientists studied one filament with antioxidants</p> <p>2 and one filament without antioxidants, correct?</p> <p>3 A. I don't remember if it was just one</p> <p>4 filament but they compare polymer with</p> <p>5 antioxidants and without oxidants.</p> <p>6 Q. Thank you. And in fact they</p> <p>7 compared those after putting it in hamsters, is</p> <p>8 that correct?</p> <p>9 A. That's correct.</p> <p>10 Q. And, Doctor, if you look with me on</p> <p>11 the last page of the Leibert article</p> <p>12 A. Yes.</p> <p>13 Q. Page 950 please. It's --</p> <p>14 A. The second last.</p> <p>15 Q. Yes, the second-to-last, top</p> <p>16 paragraph. The paragraph that charts with, "No</p> <p>17 changes".</p> <p>18 A. Yes.</p> <p>19 Q. "No changes in mechanical</p> <p>20 properties or infrared spectra were</p> <p>21 observed for any of the filaments</p> <p>22 containing antioxidants which were</p> <p>23 implanted."</p> <p>24 Did I read that correctly, sir?</p>	<p>1 made of Prolene does it, sir?</p> <p>2 MR. ANDERSON: Objection.</p> <p>3 THE DEPONENT: I can't agree with you.</p> <p>4 It says "polypropylene".</p> <p>5 BY MR. ANDERSON:</p> <p>6 Q. Move to strike as nonresponsive.</p> <p>7 I'm talking about Prolene, sir, not</p> <p>8 polypropylene but Prolene.</p> <p>9 A. But Prolene and polypropylene are</p> <p>10 the same things.</p> <p>11 Q. Dr. Iakovlev, you've already told me</p> <p>12 you're not an analytical chemist, correct?</p> <p>13 A. Correct.</p> <p>14 MR. ANDERSON: Objection.</p> <p>15 BY MR. HUTCHINSON:</p> <p>16 Q. Alright. So you'll agree that the</p> <p>17 Wood article says nothing about Prolene in it,</p> <p>18 correct?</p> <p>19 A. They don't use word "Prolene"</p> <p>20 Q. Thank you.</p> <p>21 A. That would be a correct statement.</p> <p>22 Q. Thank you.</p> <p>23 A. But it doesn't mean that they didn't</p> <p>24 use polypropylene.</p>

77 (Pages 302 to 305)

Vladimir Iakovlev, M.D.

Page 306	Page 308
<p>1 Q. Thank you. And, Doctor, if you look 2 at page 117 of the Wood article, 1117 to be exact. 3 A. Yes. 4 Q. You'll see that the authors have an 5 FTIR spectra there? 6 A. Yes. 7 Q. I'm waiting for the IT folks to 8 catch up. There it is. Thank you. 9 And, Doctor, you'll see that there's a 10 carbonyl peak at 1740. Do you see that? 11 A. I am not a material scientist. I 12 cannot interpret this graph. 13 Q. So you can't interpret whether or 14 not this oxidized -- the polypropylene oxidized in 15 this study can you, sir? 16 A. I'm not using -- I'm not familiar 17 with this technique. 18 Q. I'm sorry? 19 A. I'm not using it. I'm not familiar 20 with the technique. I cannot interpret this 21 graph. 22 Q. Thank you. In fact you can't 23 interpret any spectra in the Wood article you, 24 sir?</p>	<p>1 like the ones that you showed the jury earlier, is 2 that right? 3 A. Well my lab makes the slides. 4 Q. Okay. But more or less what you do 5 as a pathologist is that you review slides and 6 reach conclusions about a patient's illness or 7 disease, is that right? 8 A. Well I analyze them in view of the 9 history, connect clinical information with 10 pathological information and then arrive to 11 diagnosis. 12 Q. Doctor, you'll agree that it's 13 important to never mix up a patient's tissue 14 samples, correct? 15 A. Yes. 16 Q. So if we're looking for cancer 17 cells, for example, that would be a bad thing to 18 mix up a patient's tissue samples, is that 19 correct? 20 A. That's correct. 21 Q. In fact, Doctor, you would never 22 trust a pathologist who repeatedly mixed up tissue 23 samples would you? 24 MR. ANDERSON: Objection.</p>
Page 307	Page 309
<p>1 A. No. 2 Q. In fact, Doctor, you've never seen 3 an FTIR spectra for oxidized Prolene from the body 4 have you, sir? 5 A. Well, I've seen articles publishing 6 it. That's the extent of my knowledge. 7 MR. HUTCHINSON: We're going to take a 8 break, counsel. 9 THE VIDEOGRAPHER: Going off the record 10 at 4:13 p.m. 11 --- Break taken. 12 THE VIDEOGRAPHER: We're back on the 13 record at 4:22 p.m. 14 BY MR. HUTCHINSON: 15 Q. Dr. Iakovlev, we just took a break, 16 are you ready to go? 17 A. Yes. 18 Q. I want to talk about what you do at 19 the hospital in Canada where you work, okay? 20 A. Okay. 21 Q. As a pathologist you study tissue 22 that's been removed from patients, is that right? 23 A. That's correct. 24 Q. And then you make slides kind of</p>	<p>1 THE DEPONENT: Yes. I mean, this is 2 basic principles that we have to keep track of 3 what is coming from which patient. 4 BY MR. HUTCHINSON: 5 Q. It's a basic principle that tissue 6 samples should always be accounted for, is that 7 right? 8 A. Yes. 9 Q. Okay. And a pathologist should 10 never mix up tissue samples should they, sir? 11 A. No. I mean, they shouldn't mix up 12 -- I mean there are some situations when it does 13 not matter and some situation where it matters. 14 In most cases it matters. 15 Q. But if it did happen you'd be 16 skeptical of that pathologist's work wouldn't you, 17 sir? 18 A. Well it may happen at different 19 stages. It doesn't have to be pathologist's 20 fault. There are several reasons why it can 21 happen. I mean, when there are large volumes 22 things happen. We try to keep them low, as low as 23 possible. 24 Q. Doctor, have you ever mixed up</p>

78 (Pages 306 to 309)

Vladimir Iakovlev, M.D.

Page 310	Page 312
<p>1 tissue samples?</p> <p>2 A. We had some mix-ups. I mean, this</p> <p>3 happens all the time. Some of the samples I</p> <p>4 signed out we had these problems. We caught them</p> <p>5 and corrected the errors.</p> <p>6 Q. Was that at St. Michael's Hospital</p> <p>7 in Canada?</p> <p>8 A. Yes.</p> <p>9 Q. Were you reprimanded for that,</p> <p>10 Doctor?</p> <p>11 A. What do you mean?</p> <p>12 Q. Were you reprimanded by any type of</p> <p>13 medical authority for that happening, sir?</p> <p>14 A. No, I mean it wasn't my fault.</p> <p>15 Q. Doctor, you have given opinions</p> <p>16 against Ethicon in the Husky Edwards case, is that</p> <p>17 correct?</p> <p>18 A. Yes.</p> <p>19 Q. And I want to hand you what's been</p> <p>20 marked as Exhibit 9 to your deposition.</p> <p>21 ---DEFENSE EXHIBIT NO. 9: Rule 26</p> <p>22 expert report of Dr. Vladimir Iakovlev</p> <p>23 re. Jo Husky, et al., and Tonya</p> <p>24 Edwards, et al.</p>	<p>1 a picture on the bottom?</p> <p>2 A. Yes.</p> <p>3 Q. And both of these pictures were</p> <p>4 important to your opinion in the Edward's case,</p> <p>5 weren't they?</p> <p>6 A. To a degree.</p> <p>7 Q. And Ms. Edwards received an Ethicon</p> <p>8 mesh didn't she, sir?</p> <p>9 A. Yes.</p> <p>10 Q. And, Doctor, I've handed you a black</p> <p>11 Sharpie pen. Would you circle the top picture for</p> <p>12 us, please?</p> <p>13 MR. ANDERSON: I'm going to object to</p> <p>14 the relevance of all this line of questioning</p> <p>15 about Husky Edwards.</p> <p>16 BY MR. HUTCHINSON:</p> <p>17 Q. Circle the top picture for us</p> <p>18 please, sir.</p> <p>19 A. Okay.</p> <p>20 Q. And I want you to write down at the</p> <p>21 bottom "Edwards Ethicon" so that the jury can</p> <p>22 understand it and review it. And, Dr. Iakovlev,</p> <p>23 you've also given testimony against American</p> <p>24 Medical Systems, is that correct?</p>
Page 311	Page 313
<p>1 BY MR. HUTCHINSON:</p> <p>2 Q. This is a copy of the report that</p> <p>3 you prepared against Ethicon. Is that right, sir?</p> <p>4 A. Yes.</p> <p>5 Q. And you signed and dated this</p> <p>6 report, is that correct?</p> <p>7 A. Yes. I don't see a date of this</p> <p>8 report.</p> <p>9 Q. Well, I want to make sure I have the</p> <p>10 right copy so let's look at page 74. That's your</p> <p>11 signature on page 74, is that correct, sir?</p> <p>12 A. Yes, it is.</p> <p>13 Q. And Doctor, certainly you proofread</p> <p>14 this before you signed it, correct?</p> <p>15 A. Yes, I do read reports when I sign</p> <p>16 them.</p> <p>17 Q. And, Doctor, let's look at page 22</p> <p>18 of the report that you did for Ms. Edwards. Are</p> <p>19 you there?</p> <p>20 A. Yes.</p> <p>21 Q. And, Doctor, you identify two</p> <p>22 pictures as Ms. Edward's mesh explant, correct?</p> <p>23 A. That's correct.</p> <p>24 Q. And there's a picture on the top and</p>	<p>1 A. That's correct.</p> <p>2 Q. I want to hand you what's been</p> <p>3 marked as Exhibit 10 to your deposition.</p> <p>4 A. Yes.</p> <p>5 ---DEFENSE EXHIBIT NO. 10: Addendum to</p> <p>6 the Rule 26 expert report of</p> <p>7 Dr. Vladimir Iakovlev re. Lisa Marie</p> <p>8 Fontes, et al.</p> <p>9 BY MR. HUTCHINSON:</p> <p>10 Q. And this is the document or the</p> <p>11 report that you signed for Lisa Marie Fontes, is</p> <p>12 that correct? Doctor?</p> <p>13 A. Um, on page 10 I see John Serrano</p> <p>14 specimen.</p> <p>15 Q. No, we're talks about Exhibit 10.</p> <p>16 That's Exhibit 10.</p> <p>17 A. Yes.</p> <p>18 Q. My question is, this is the report</p> <p>19 that you prepared against American Medical Systems</p> <p>20 for Lisa Marie Fontes, is that correct?</p> <p>21 A. That's correct.</p> <p>22 Q. And Ms. Fontes received an American</p> <p>23 Medical Systems mesh didn't she, sir?</p> <p>24 A. Yes.</p>

79 (Pages 310 to 313)

Vladimir Iakovlev, M.D.

Page 314	Page 316
<p>1 Q. And that's a company that's</p> <p>2 completely different from Ethicon isn't it?</p> <p>3 A. Yes.</p> <p>4 Q. And, Doctor, if you look on page 18</p> <p>5 of that report, figure 6. Do you see that figure,</p> <p>6 Doctor? Dr. Iakovlev, do you see figure 6 on page</p> <p>7 18?</p> <p>8 A. Well there are two figures in figure</p> <p>9 6, there is top row figures and bottom row.</p> <p>10 Q. And, Doctor, if you'll get your pen</p> <p>11 and circle the bottom left photograph for the jury</p> <p>12 please. Bottom left.</p> <p>13 A. Yes, but the entire figure contains</p> <p>14 two panels, upper panel and lower panel.</p> <p>15 Q. I understand. And, Doctor, your</p> <p>16 lawyer is going to get to ask you some question.</p> <p>17 A. Okay.</p> <p>18 Q. But I'm just asking you just the</p> <p>19 bottom left picture. You circled two pictures.</p> <p>20 Just the bottom left picture.</p> <p>21 A. It's the same picture. One is</p> <p>22 labeled one is not.</p> <p>23 Q. And, Doctor, will you please write</p> <p>24 "AMS" by that photograph?</p>	<p>1 here, yes, they are. Not the top one here.</p> <p>2 Q. And that tissue couldn't have</p> <p>3 belonged to Ms. Edwards who had an Ethicon mesh</p> <p>4 and somebody else who had an AMS mesh could it?</p> <p>5 A. No.</p> <p>6 Q. In fact --</p> <p>7 A. Wait a second. This is not specific</p> <p>8 to a specific patient because it does not identify</p> <p>9 any patient under these figures. What it does it</p> <p>10 combines representative images of thrombosed</p> <p>11 vessels. One of them is Ethicon, one of them is</p> <p>12 AMS. This one is for specific patient and, yes,</p> <p>13 one of the images in this specific report was from</p> <p>14 Ethicon the other one from AMS.</p> <p>15 Q. Right. In fact, Doctor, you</p> <p>16 included an AMS picture in your Ethicon report</p> <p>17 didn't you, sir?</p> <p>18 A. Did I say that it was just limited</p> <p>19 to AMS samples?</p> <p>20 Q. Doctor, I need you is to stick with</p> <p>21 me please on page 18.</p> <p>22 A. Yes, it was --</p> <p>23 Q. And I need you to show the jury --</p> <p>24 A. So --</p>
Page 315	Page 317
<p>1 A. Um, I did not say that that specific</p> <p>2 is AMS. Why are you making me to do something</p> <p>3 which I did not do?</p> <p>4 MR. ANDERSON: Don't do it.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. Dr. Iakovlev, would you look at the</p> <p>7 bottom of that paragraph please and you write "AMS</p> <p>8 mesh explants." Don't you, sir?</p> <p>9 A. Yes, but there are two panels, one</p> <p>10 is panel on the top and then one panel on the</p> <p>11 bottom.</p> <p>12 Q. Move to strike as nonresponsive.</p> <p>13 You write "AMS mesh explants", correct?</p> <p>14 A. That's correct.</p> <p>15 Q. And in fact, Doctor, I want you to</p> <p>16 hold these up for the jury, please. And in your</p> <p>17 right hand you have an AMS explant mesh, correct?</p> <p>18 A. Yes, with two panels.</p> <p>19 Q. And in your left hand you have an</p> <p>20 Ethicon mesh don't you, sir?</p> <p>21 A. Yes, I do.</p> <p>22 Q. And, Doctor, those pictures that</p> <p>23 you've circled are identical aren't they?</p> <p>24 A. The bottom one here and the top one</p>	<p>1 Q. Excuse me, sir, I'm going to get to</p> <p>2 ask the questions, okay?</p> <p>3 MR. ANDERSON: Well, he's trying to</p> <p>4 answer your questions.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. And, Doctor, I need you to show that</p> <p>7 picture right beside your Ethicon report.</p> <p>8 MR. ANDERSON: He just did that.</p> <p>9 THE DEPONENT: I just did it.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. And, Doctor, write "AMS".</p> <p>12 MR. FREESE: No, we're not going to be</p> <p>13 modifying exhibits. They say what they say.</p> <p>14 BY MR. HUTCHINSON:</p> <p>15 Q. Absolutely.</p> <p>16 MR. ANDERSON: If you want to write it</p> <p>17 on there you write it on there. If you want to</p> <p>18 show it to the jury you show it to the jury but</p> <p>19 you're not going to make him do it.</p> <p>20 BY MR. HUTCHINSON:</p> <p>21 Q. And, Doctor, I've written "AMS" to</p> <p>22 at the bottom. Would you publish that to the jury</p> <p>23 please?</p> <p>24 A. Yes, but that's not what I'm saying.</p>

80 (Pages 314 to 317)



Vladimir Iakovlev, M.D.

Page 318	Page 320
<p>1 Q. And in fact, Doctor, on the bottom</p> <p>2 of figure 6, and if the camera would zoom in</p> <p>3 please, you write "AMS mesh explants." Don't you,</p> <p>4 sir? That's what you write, correct?</p> <p>5 A. Yes, one of them is AMS.</p> <p>6 Q. And they can't be the same mesh from</p> <p>7 one from AM and one from Ethicon can it, sir?</p> <p>8 A. Well they are.</p> <p>9 Q. Is that a mistake, Doctor?</p> <p>10 A. Which mistake? There might be "s"</p> <p>11 as a plural tense -- sorry, as a plural form is an</p> <p>12 error, a typo.</p> <p>13 Q. Which is a typo?</p> <p>14 A. The "explants".</p> <p>15 Q. But, Doctor, you'll agree that the</p> <p>16 AMS mesh picture that you circled is identical to</p> <p>17 your AM -- to your report in the Edward's case,</p> <p>18 correct?</p> <p>19 A. Well, we clearly see that it's not</p> <p>20 AMS it's Ethicon case. It's Ethicon case, yes.</p> <p>21 Q. But you labelled it as an AMS</p> <p>22 explant, correct?</p> <p>23 A. Well, I included two pictures here</p> <p>24 and it was probably a typo that "explants", one of</p>	<p>1 MR. FREESE: I might be. I don't know</p> <p>2 yet.</p> <p>3 BY MR. HUTCHINSON:</p> <p>4 Q. Dr. Iakovlev, page 18.</p> <p>5 A. Yes.</p> <p>6 Q. The picture on the top left and the</p> <p>7 picture on the bottom left, that's the same tissue</p> <p>8 sample isn't it, sir?</p> <p>9 A. I don't know.</p> <p>10 Q. It has the same smudge on it in the</p> <p>11 middle doesn't it, sir?</p> <p>12 A. You cannot go by smudge. You have</p> <p>13 to go by labels and I would have to see original</p> <p>14 slides to determine that.</p> <p>15 Q. Doctor, you also gave opinions</p> <p>16 against Ethicon in the Bellew case didn't you,</p> <p>17 sir?</p> <p>18 A. Yes, I did.</p> <p>19 Q. I want to hand you what we'll mark</p> <p>20 as Exhibit 11 in the Bellew case.</p> <p>21 ---DEFENSE EXHIBIT NO. 11: Rule 26</p> <p>22 expert report of Vladimir Iakovlev, re.</p> <p>23 Diane Bellew.</p> <p>24</p>
Page 319	Page 321
<p>1 them is clearly Ethicon. And that does not</p> <p>2 identify which patient. These are representative</p> <p>3 images to show thrombosis rather than to attribute</p> <p>4 specific findings to specific patient so there is</p> <p>5 a big difference. Demonstrative purpose or</p> <p>6 specific diagnostic purpose.</p> <p>7 Q. And, Doctor -- but, Doctor, let's</p> <p>8 look on page 18. And I want you to show the jury</p> <p>9 the two samples that you're looking at. Show the</p> <p>10 jury.</p> <p>11 MR. ANDERSON: How many times do you</p> <p>12 want him to show the jury?</p> <p>13 MR. HUTCHINSON: I know you're upset.</p> <p>14 MR. ANDERSON: Nobody's upset. You</p> <p>15 think you've got your big gotcha moment. It</p> <p>16 doesn't mean nothing to me.</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. Dr. Iakovlev, that's the same tissue</p> <p>19 sample isn't it, sir?</p> <p>20 MR. FREESE: Move to strike your sidebar</p> <p>21 comment. Nobody is upset. You have three people</p> <p>22 laughing over on this side of the table.</p> <p>23 MR. HUTCHINSON: Are you finished?</p> <p>24 THE DEPONENT: What do you mean?</p>	<p>1 BY MR. HUTCHINSON:</p> <p>2 Q. In fact, Doctor, if you look at page</p> <p>3 15 you say at the top "All images are of explanted</p> <p>4 Ethicon mesh unless indicated otherwise." Do you</p> <p>5 see that?</p> <p>6 A. Yes, I do.</p> <p>7 Q. And, Doctor, if we turn to page 33</p> <p>8 of your report against Ethicon in the Bellew case,</p> <p>9 show the jury the picture in the top.</p> <p>10 A. Yes. So we know it's from Edward's</p> <p>11 case.</p> <p>12 Q. And, Doctor, that's the exact same</p> <p>13 picture that you used in your report against AMS,</p> <p>14 isn't it?</p> <p>15 A. Yes, to demonstrate thrombosis.</p> <p>16 Q. And in fact in your AMS report</p> <p>17 that's the exact same picture that you labelled as</p> <p>18 an AMS mesh explant, correct?</p> <p>19 A. Well, I don't know if --</p> <p>20 MR. ANDERSON: Object to the form of the</p> <p>21 question.</p> <p>22 THE DEPONENT: I don't know if it was</p> <p>23 labelled for both or just for the top. I cannot</p> <p>24 remember now what happened in 2014.</p>

81 (Pages 318 to 321)

Vladimir Iakovlev, M.D.

Page 322	Page 324
<p>1 BY MR. HUTCHINSON:  2 Q. Doctor, let's look at Ms. Ramirez's  3 report. It's maybe Exhibit 1.  4 A. Okay. Here it is.  5 Q. Doctor, you signed and dated  6 Ms. Ramirez's report, didn't you?  7 A. Yes, I did.  8 Q. And let's look at page 20.  9 A. Page 20 of case specific or page 20  10 --  11 Q. Of case specific, yes, sir. Or I'm  12 sorry, general.  13 A. Yes.  14 Q. And you write, "All photographs are  15 of explanted Ethicon mesh."  16 MR. FREESE: Wait.  17 MR. ANDERSON: Your numbers on this  18 exhibit that you gave me are different. The page  19 numbers are different.  20 THE DEPONENT: It's the general.  21 MR. ANDERSON: Oh it's the general.  22 Okay.  23 BY MR. HUTCHINSON:  24 Q. Dr. Iakovlev, on page 20 of your</p>	<p>1 THE DEPONENT: Again, could be typo.  2 BY MR. HUTCHINSON:  3 Q. Doctor, you also have given  4 testimony for the plaintiffs against Boston  5 Scientific haven't you?  6 MR. ANDERSON: Objection, asked and  7 answered.  8 THE DEPONENT: Yes, I did.  9 BY MR. HUTCHINSON:  10 Q. I want to hand you what we'll mark  11 as the next exhibit. Defense Exhibit 12.  12 ---DEFENSE EXHIBIT NO. 12: Rule 26  13 expert report of Dr. Vladimir Iakovlev  14 re. Amal Eghnayem.  15 BY MR. HUTCHINSON:  16 Q. Are you there with me?  17 A. Yes.  18 Q. And, Doctor, this is the report that  19 you did for the Eghnayem case, is that right?  20 A. That's correct.  21 Q. And you signed and dated this report  22 didn't you, sir?  23 A. Yes, I did.  24 Q. And, Doctor, if you look at page 16</p>
Page 323	Page 325
<p>1 Ramirez report for Jennifer Ramirez you write,  2 "All photographs are of explanted Ethicon  3 devices." Correct?  4 A. That's correct.  5 Q. And, Doctor, if you look at page 32  6 of your report, turn there with me please.  7 A. Yes.  8 Q. Show that to the jury.  9 A. Yes, it's the same pictures we saw  10 before.  11 Q. That's the exact same picture that  12 you included in your report against AMS, is that  13 correct?  14 A. One of them.  15 Q. And, Doctor, that's the exact  16 picture that you included in your AMS report that  17 you labelled an AMS mesh, correct?  18 A. Well, we agreed that there are two  19 images and one is labelled as AMS, at least one,  20 and the other one, as we agreed, is Ethicon from  21 Ms. Edward's case.  22 Q. That was just a mistake wasn't it,  23 Doctor?  24 MR. ANDERSON: Objection.</p>	<p>1 of the report.  2 A. Yes.  3 Q. Your write, "All images are of  4 explanted Boston Scientific mesh unless indicated  5 others." Did I read that correctly, sir?  6 A. Yes, you did.  7 Q. And if you go to page 36 of your  8 Boston Scientific report.  9 A. 36?  10 Q. Yes, sir.  11 A. Yes.  12 Q. And using that black pen would you  13 circle the bottom image for us please?  14 A. This one?  15 Q. And, Doctor, why don't you write  16 "Boston Scientific" at the bottom?  17 MR. FREESE: No, we're not going to  18 write anything.  19 THE DEPONENT: I'm not writing anything.  20 I circled it but I'm not writing.  21 BY MR. HUTCHINSON:  22 Q. Doctor, would you hand me the  23 document please? You're refusing to write "Boston  24 Scientific" at the bottom, is that correct?</p>

82 (Pages 322 to 325)

Vladimir Iakovlev, M.D.

Page 326	Page 328
<p>1 MR. ANDERSON: You can't ask him to 2 alter the exhibits. If you want to do it you can. 3 BY MR. HUTCHINSON: 4 Q. Doctor, are you refusing to write 5 Boston Scientific -- 6 MR. ANDERSON: Don't answer the 7 question. Don't answer the question. 8 MR. FREESE: He's refusing to do it. 9 BY MR. ANDERSON: 10 Q. Doctor, you refuse to write "Boston 11 Scientific" at the bottom didn't you, sir? 12 MR. FREESE: No, he was instructed not 13 to do it. 14 MR. HUTCHINSON: Well I'm going to get a 15 yes or no from him on that question. 16 MR. FREESE: I'm telling you he was 17 instructed not to do it. You're asking him to 18 modify irrelevant exhibits and we're not going to 19 go down that path. 20 BY MR. HUTCHINSON: 21 Q. Dr. Iakovlev, are you refusing to 22 answer the question based on counsel's advice? 23 MR. FREESE: There's no question 24 pending. You asked him to write something or</p>	<p>1 manufacturers. 2 Q. And, Doctor, in your right hand your 3 report you tell whoever is going to read it that 4 all images are of explanted Boston Scientific mesh 5 don't you, sir? 6 A. Well -- 7 MR. ANDERSON: Objection to form and 8 relevance. 9 THE DEPONENT: -- apparently there was 10 missed information -- missed labelling here that 11 it's from Boston Scientific. 12 BY MR. HUTCHINSON: 13 Q. Thank you. And in fact, Doctor, if 14 you look in the documents in your right hand, I'm 15 sorry, your left hand, those are Ethicon meshes 16 aren't they, sir? 17 A. Well I'm not stating that this is 18 Boston Scientific or this is Ethicon. The only 19 thing that is missing one of the labels misses 20 that it's a different manufacturer, that's it. 21 Q. Doctor, let's look at what you write 22 on page 16 of the report in your left hand. 23 A. Well, I told you that -- 24 MR. ANDERSON: Objection, asked and</p>
Page 327	Page 329
<p>1 modify or alter an exhibit and we're refusing to 2 do that. 3 BY MR. HUTCHINSON: 4 Q. And, Dr. Iakovlev, are you following 5 the lawyers' instructions? 6 MR. ANDERSON: Oh my gosh. 7 THE DEPONENT: Yes. 8 BY MR. HUTCHINSON: 9 Q. Thank you. And, Doctor, I want you 10 to compare the picture in your Boston Scientific 11 report to the picture in Ms. Bellew's report, 12 which is Exhibit number 11 on page 40. 13 A. Yes. 14 Q. And why don't you show it to the 15 jury alongside the one that you did for Boston 16 Scientific? 17 A. Yes. 18 Q. Alongside the one that you did for 19 Boston Scientific. 20 A. Yeah, they're the same images. 21 Q. Yeah. And, Doctor, in your right 22 hand you have a report that you prepared for 23 Boston Scientific, correct? 24 A. Yes, but I use images from different</p>	<p>1 answered. 2 THE DEPONENT: -- one of the reports is 3 missing that extra information. And it doesn't 4 matter because it does not state that this is 5 specific manufacturer, it just demonstrates 6 histological feature. Manufacturer doesn't 7 matter. 8 BY MR. HUTCHINSON: 9 Q. Dr. Iakovlev, in your report that 10 you have in your hand now, page 15, you write, 11 "All images are of explanted Ethicon mesh." 12 Correct? 13 A. That's correct. I tried to do as 14 precise as possible, but since the focus is not on 15 specific manufacturer but on the histological 16 feature maybe some labels were not expanded 17 appropriately. 18 Q. And, Doctor, let's look at some more 19 of those labels. Let's look in the Eghnayem 20 figure 23(B). 21 A. Now I'm lost which -- 22 Q. Eghnayem, Exhibit number 12. 23 A. Yes. 24 Q. Figure 23(B). And I want you to</p>

83 (Pages 326 to 329)

Vladimir Iakovlev, M.D.

Page 330	Page 332
<p>1 compare it to what you did in the Bellew case on 2 page 67. 3 MR. ANDERSON: Objection. Relevance and 4 form. 5 THE DEPONENT: 23(B). And you want me 6 to compare which one? 7 BY MR. HUTCHINSON: 8 Q. Figure 23(B) on page 51 of your 9 Eghnayem report -- 10 A. With? 11 Q. -- with figure 25(C) on page 67 of 12 your Bellew report. 13 A. Figure -- sorry, page? 14 Q. That's okay, Doctor, let me do it 15 again. I want you to compare figure 23(B) of your 16 Boston Scientific report to figure 25(C) of your 17 Ethicon report on page 67. 18 A. Yes. 19 Q. Doctor, will you show the jury those 20 two images please? 21 A. So they're exactly the same images. 22 Q. And, Doctor, in fact the one on the 23 top is from Boston Scientific and the one you have 24 on the bottom is from Ethicon. Is that correct,</p>	<p>1 specific manufacturer I'm demonstrating a 2 histological feature which is common for all 3 polypropylene meshes, doesn't matter which 4 manufacturer. Can be coming from AMS, from Boston 5 Scientific, from Ethicon. All of the meshes 6 degrade. They will all show the same features. 7 Q. Move to strike as nonresponsive. 8 Doctor, let's look at 28(A) in your 9 Boston Scientific report and compare it to 30(A) 10 in your Ethicon report. Those images are 11 identical aren't they? 12 A. Which ones again? 13 MR. ANDERSON: Objection. 14 BY MR. HUTCHINSON: 15 Q. 28(A) in your Boston Scientific 16 report and 30(A) in your Ethicon report. 17 MR. FREESE: Would you identify them 18 by -- 19 MR. HUTCHINSON: Page number? 20 MR. FREESE: And the party name too 21 please. 22 BY MR. HUTCHINSON: 23 Q. Those images are identical aren't 24 they, sir?</p>
Page 331	Page 333
<p>1 sir? 2 A. Well, I did not say that the sample 3 is from one and from the other. 4 Q. In fact, Doctor, you did write that 5 all images are of Ethicon -- are of Boston 6 Scientific unless otherwise indicated, correct? 7 MR. ANDERSON: Objection. 8 THE DEPONENT: That was my intent. 9 BY MR. HUTCHINSON: 10 Q. Thank you 11 A. But for some labels this information 12 didn't enter it was not entered. 13 Q. It was not what? 14 A. Entered. 15 Q. Entered? 16 A. Yes. 17 Q. Entered by whom? 18 A. By me. 19 Q. Alright. Doctor, let's look at the 20 next page. Page 52 of your Boston Scientific 21 report and compare it to page 68 of your Ethicon 22 report. 23 A. Yeah, it's the test same image. 24 Again, I'm not demonstrating a feature of a</p>	<p>1 MR. FREESE: Object. Until you identify 2 what reports in which cases and then we object to 3 the relevance. 4 BY MR. HUTCHINSON: 5 Q. And, Dr. Iakovlev, I'm referring to 6 your Boston Scientific report, page 58, and your 7 Ethicon report, page 74. 8 A. Yes. 9 Q. Those images are identical aren't 10 they, sir? 11 A. That's correct. 12 Q. And, Doctor, if we look at the 13 images on page 59 of your Boston Scientific report 14 to page 75 of your Ethicon report, those images 15 are identical aren't they, sir? 16 A. Yeah. I'm showing the same feature. 17 I'm using different manufacturers because it 18 doesn't matter, I'm showing features not 19 manufacturers. 20 Q. And, Doctor, if we look at page 60 21 of your Boston Scientific report and compare that 22 to page 76 of your Ethicon report, those images 23 are identical aren't they, sir? 24 A. Yes, they are.</p>

84 (Pages 330 to 333)

Vladimir Iakovlev, M.D.

Page 334	Page 336
<p>1 Q. And, Doctor, if we look at page 61</p> <p>2 of your Boston Scientific report and compare it to</p> <p>3 page 77 of your Ethicon report those images are</p> <p>4 identical aren't they, sir?</p> <p>5 A. All transmission electron images are</p> <p>6 identical because I examined only five or six</p> <p>7 specimens only. Only I think one or two were</p> <p>8 Ethicon and others were from other manufacturers.</p> <p>9 Q. Move to strike as nonresponsive.</p> <p>10 My question, sir, is that those images</p> <p>11 are identical aren't they?</p> <p>12 A. Yes. They show -- as I said, I did</p> <p>13 very little transmission electron microscopy work.</p> <p>14 There were just few specimens. They are the same.</p> <p>15 Q. And, Doctor, let's look at page 62</p> <p>16 of your Boston Scientific report and compare it to</p> <p>17 page 78 of your Ethicon report.</p> <p>18 A. Yes.</p> <p>19 Q. 62 of the Boston Scientific report</p> <p>20 and compare that to page 78 of your Ethicon</p> <p>21 report?</p> <p>22 A. Yes.</p> <p>23 Q. Those images are identical aren't</p> <p>24 they, sir?</p>	<p>1 A. But the feature is the same.</p> <p>2 Q. And, Doctor, you've given testimony</p> <p>3 in the White case haven't you, sir?</p> <p>4 A. Yes.</p> <p>5 Q. And I want to hand you what we'll</p> <p>6 mark as Exhibit 13 to your deposition.</p> <p>7 ---DEFENSE EXHIBIT NO. 13: Report by</p> <p>8 Dr. Iakovlev titled</p> <p>9 "Clinico-pathological Correlation of</p> <p>10 Complications Experienced by Ms.</p> <p>11 Virginia White".</p> <p>12 BY MR. HUTCHINSON:</p> <p>13 Q. This is your expert report that was</p> <p>14 signed and dated by you, is that correct?</p> <p>15 A. That's correct.</p> <p>16 Q. And, Doctor, on page 2 at the top</p> <p>17 you write in your report, "Ethicon TVT sling was</p> <p>18 placed for incontinence." Did I read that</p> <p>19 correctly?</p> <p>20 MR. ANDERSON: Objection.</p> <p>21 MR. FREESE: Hold on. Let's identify --</p> <p>22 you said the White case. White versus who?</p> <p>23 MR. HUTCHINSON: White versus Ethicon.</p> <p>24</p>
Page 335	Page 337
<p>1 MR. ANDERSON: Objection.</p> <p>2 THE DEPONENT: As I said, all</p> <p>3 transmission electron microscopy images are</p> <p>4 identical. I had very limited amount of</p> <p>5 photographs for transmission electron microscopy.</p> <p>6 They are all copied from all the same reports.</p> <p>7 BY MR. HUTCHINSON:</p> <p>8 Q. In fact, Doctor, if we look at page</p> <p>9 63 of your Boston Scientific report and compare</p> <p>10 that to page 79 of your Ethicon report those</p> <p>11 images are identical aren't they, sir?</p> <p>12 A. Well I just told you, all</p> <p>13 transmission electron microscopy images are</p> <p>14 identical for either manufacturer. Because,</p> <p>15 again, it doesn't matter what manufacturer I'm</p> <p>16 showing the features of degradation.</p> <p>17 Q. Doctor, those pictures that you're</p> <p>18 showing us they can't be of both a Boston</p> <p>19 Scientific and an Ethicon mesh at the same time</p> <p>20 can they?</p> <p>21 MR. ANDERSON: Objection.</p> <p>22 THE DEPONENT: No, of course not.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. Thank you.</p>	<p>1 BY MR. HUTCHINSON:</p> <p>2 Q. Dr. Iakovlev, you write on page 2,</p> <p>3 "Ethicon TVT sling was placed for incontinence."</p> <p>4 Correct?</p> <p>5 MR. ANDERSON: Objection to the entire</p> <p>6 line of questions. It has nothing to do with</p> <p>7 Ramirez but object to that specific question as</p> <p>8 well.</p> <p>9 BY MR. HUTCHINSON:</p> <p>10 Q. Dr. Iakovlev?</p> <p>11 A. Yes, I do see it.</p> <p>12 Q. And that's what you wrote, correct?</p> <p>13 A. That's correct.</p> <p>14 Q. And you're telling everybody --</p> <p>15 A. Well it's not just wrote, this is a</p> <p>16 clinical summary. I was copying it from medical</p> <p>17 records.</p> <p>18 Q. Okay. And, Doctor, Ethicon is the</p> <p>19 only company that makes a TVT sling aren't they?</p> <p>20 A. People use that term flexibly. So</p> <p>21 clinician just frequently say "TVT" for any sling.</p> <p>22 Q. Move to strike as nonresponsive.</p> <p>23 MR. ANDERSON: May not like the answer</p> <p>24 but --</p>

85 (Pages 334 to 337)



Vladimir Iakovlev, M.D.

Page 338	Page 340
<p>1 BY MR. HUTCHINSON:</p> <p>2 Q. Dr. Iakovlev, Ethicon is the only</p> <p>3 company that makes a brand name TVT sling,</p> <p>4 correct?</p> <p>5 A. Brand name TVT sling, yes, but the</p> <p>6 term is uses loosely by clinicians.</p> <p>7 Q. Okay. And, Doctor, you gave</p> <p>8 testimony under oath that Ms. White received a TVT</p> <p>9 sling didn't you, sir?</p> <p>10 A. Well I copied it from the records.</p> <p>11 Q. And, Doctor, did you ever look at</p> <p>12 the medical records to make sure that they were</p> <p>13 accurate?</p> <p>14 A. What do you mean? I'm copying it</p> <p>15 from the records.</p> <p>16 Q. Doctor, I want to hand you what</p> <p>17 we'll mark as Exhibit 14 to your deposition.</p> <p>18 ---DEFENSE EXHIBIT NO. 14: Medical</p> <p>19 report from Mercy Hospital Northwest</p> <p>20 Arkansas re. Virginia White. Bates</p> <p>21 labelled WHITEV_SMAMM_MDR00027.</p> <p>22 BY MR. HUTCHINSON:</p> <p>23 Q. This is the medical record for</p> <p>24 Ms. White. And if you show the jury please in the</p>	<p>1 BY MR. HUTCHINSON:</p> <p>2 Q. Dr. Iakovlev, my question to you is,</p> <p>3 this medical record for the White case that you</p> <p>4 gave opinions against Ethicon it says,</p> <p>5 "Manufacturer: Boston Scientific". Correct?</p> <p>6 A. Yes, I copied it from the records.</p> <p>7 Q. And, Doctor, would you show that to</p> <p>8 the jury please? And right in the middle is where</p> <p>9 it says, "Manufacturer: Boston Scientific." Is</p> <p>10 that right?</p> <p>11 A. Yeah, this specific document says</p> <p>12 Boston Scientific.</p> <p>13 Q. And, Doctor, you gave testimony</p> <p>14 under oath that Ms. White received a product other</p> <p>15 than Boston Scientific didn't you, sir?</p> <p>16 MR. FREESE: Well she did according to</p> <p>17 the medical record. Why are you ignoring the top</p> <p>18 of the exhibit?</p> <p>19 BY MR. HUTCHINSON:</p> <p>20 Q. Dr. Iakovlev, you testified under</p> <p>21 oath that Ms. White received a TVT sling didn't</p> <p>22 you, sir?</p> <p>23 A. Yes, I did.</p> <p>24 Q. And, Doctor, according to the</p>
Page 339	Page 341
<p>1 middle of the document where we're looking at</p> <p>2 under the word "Implants". Would you show the</p> <p>3 jury that for us please?</p> <p>4 A. I have to see where it is.</p> <p>5 Q. Right in the middle.</p> <p>6 A. Yes, I see it.</p> <p>7 Q. Okay. And, Doctor, the medical</p> <p>8 record for Ms. White says, "Inventory: Sling</p> <p>9 transvaginal advent fit. Implant name:</p> <p>10 Advantage. Manufacturer: Boston Scientific</p> <p>11 Corporation." Did I read that correctly?</p> <p>12 A. Just let me examine the entire</p> <p>13 document.</p> <p>14 MR. FREESE: Object to the question.</p> <p>15 You don't have the medical records so you selected</p> <p>16 one.</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. Your objection is noted.</p> <p>19 MR. ANDERSON: Of course it's noted,</p> <p>20 she's typing it down. I would hope so.</p> <p>21 MR. HUTCHINSON: Your comment is noted</p> <p>22 too.</p> <p>23 MR. ANDERSON: I would hope so. She's</p> <p>24 typing it.</p>	<p>1 medical record for Ms. White she received a</p> <p>2 product manufactured by Boston Scientific didn't</p> <p>3 she, sir?</p> <p>4 MR. FREESE: Object to the question,</p> <p>5 misstates the record. Are you just going to</p> <p>6 ignore what's right above it?</p> <p>7 THE DEPONENT: No, I can see one is a</p> <p>8 Boston Scientific product, the other is an Ethicon</p> <p>9 product.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. In fact, Doctor, the Gynemesh that's</p> <p>12 not a sling used to treat incontinence is it, sir?</p> <p>13 MR. ANDERSON: Objection.</p> <p>14 THE DEPONENT: Well let me just read the</p> <p>15 whole thing again.</p> <p>16 MR. FREESE: Can we have a standing</p> <p>17 objection on anything that is White -- all the</p> <p>18 stuff that's non-Ramirez specific we don't have</p> <p>19 complete records. We don't --</p> <p>20 MR. HUTCHINSON: You have a standing</p> <p>21 objection, counsel.</p> <p>22 MR. FREESE: Thank you.</p> <p>23 MR. HUTCHINSON: You're welcome.</p> <p>24</p>

86 (Pages 338 to 341)

Vladimir Iakovlev, M.D.

Page 342	Page 344
<p>1 BY MR. HUTCHINSON:  2 Q. Dr. Iakovlev, are you still  3 reviewing that one page medical record?  4 MR. FREESE: Objection, argumentative.  5 THE DEPONENT: Well, I review  6 everything.  7 BY MR. HUTCHINSON:  8 Q. Dr. Iakovlev, are you still  9 reviewing that one page medical record?  10 MR. ANDERSON: Objection. Ask your  11 question.  12 BY MR. HUTCHINSON:  13 Q. That's my question, are you still  14 reviewing that one-page medical record?  15 MR. ANDERSON: He said he's ready.  16 THE DEPONENT: I'm ready.  17 BY MR. HUTCHINSON:  18 Q. Dr. Iakovlev, you testified under  19 oath about the wrong product that Ms. White  20 received didn't you, sir.  21 MR. ANDERSON: Objection. Where's the  22 testimony?  23 BY MR. HUTCHINSON:  24 Q. You can answer.</p>	<p>1 BY MR. HUTCHINSON:  2 Q. Doctor, let's look at page -- it's  3 actually page 6. We're under the  4 clinico-pathological correlation. Are you there  5 with me, Dr. Iakovlev?  6 A. You would have to give me time so I  7 review the document and then I can answer your  8 questions.  9 Alright. So --  10 Q. Dr. Iakovlev, I'm sorry I don't have  11 a question pending. I'm not interrupting him but  12 I don't have a question pending.  13 MR. FREESE: That's fine.  14 MR. HUTCHINSON: Well, you're looking at  15 me that way and I was going to say --  16 MR. FREESE: No, I wasn't saying  17 anything. I was looking because I didn't think  18 there was a question pending.  19 BY MR. HUTCHINSON:  20 Q. Dr. Iakovlev, turn with me to page 6  21 under "Clinico-pathological correlation". Are you  22 there? Dr. Iakovlev, are you there?  23 A. Yes, I am.  24 Q. And you write, first sentence:</p>
Page 343	Page 345
<p>1 A. Well, I'm copying here from the  2 records in the summary. It's not my testimony,  3 it's not my opinion. That's something I copied  4 from the records.  5 Q. Doctor, you gave opinions in the  6 White case about a TVT sling, correct?  7 A. That's -- well, I have to read the  8 whole. I don't remember the whole case. Trying  9 -- you're plucking one specific fact. I have to  10 review the whole report.  11 MR. FREESE: Well more importantly  12 you're referring to testimony, Chad, and you're  13 refusing to show the witness the testimony you say  14 he gave.  15 BY MR. HUTCHINSON:  16 Q. Well, let's look at page --  17 MR. FREESE: And you hand him one page  18 of Ms. White's medical records.  19 BY MR. HUTCHINSON:  20 Q. I'll tell you what, Doctor, I'll  21 make it easy for you. Let's look at the first  22 sentence --  23 MR. ANDERSON: Object to the form of the  24 question.</p>	<p>1 "As described in the clinical  2 records Ms. White had rectocele repair  3 with Gynemesh and TVT retropubic  4 suburethral sling placement for mixed  5 incontinence."  6 Did I read that correctly?  7 A. That's correct.  8 Q. And, Doctor, this report that you  9 have in front of you for the White case is a  10 report that contains opinions about Ethicon,  11 correct?  12 A. That's correct.  13 Q. And, Doctor, if you look at the  14 medical record that we've marked as Exhibit 13 --  15 14 to your deposition?  16 A. Yes.  17 Q. You will agree that in the middle it  18 says, "Manufacturer, Boston Scientific" when it  19 discusses the sling?  20 A. This is not correct. It says  21 "Gynecare Gynemesh". What I received from  22 Ms. White is posterior mesh which was Gynemesh.  23 And I gave opinions regarding Gynemesh  24 manufactured by Ethicon because I received only</p>

87 (Pages 342 to 345)

Vladimir Iakovlev, M.D.

Page 346	Page 348
<p>1 Ethicon product.</p> <p>2 Q. And, Doctor, if you would -- for the</p> <p>3 benefit of the jury I'm going to ask that you show</p> <p>4 the jury that --</p> <p>5 MR. ANDERSON: No, if you want to show</p> <p>6 the jury for something you need to bring your</p> <p>7 trial consultant or you bring your own thing.</p> <p>8 You're going to stop making him walk around and</p> <p>9 parade this thing like a sandwich boy. Now, if</p> <p>10 you want to show him something you show it to him.</p> <p>11 He's not showing you anything else.</p> <p>12 MR. HUTCHINSON: He's got Exhibit 14 in</p> <p>13 front of him, counsel.</p> <p>14 MR. ANDERSON: Well, he'll hand it back</p> <p>15 to you. Here you go. Show whatever you want.</p> <p>16 MR. HUTCHINSON: No.</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. Dr. Iakovlev, here is Exhibit 14.</p> <p>19 MR. ANDERSON: He's not going to be a</p> <p>20 poster boy no more. Don't do it.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. Dr. Iakovlev, would you take Exhibit</p> <p>23 14 and show the jury where it says the sling that</p> <p>24 Ms. White received was a TVT sling?</p>	<p>1 opinions in the White case that TVT was defective,</p> <p>2 correct?</p> <p>3 MR. ANDERSON: Objection.</p> <p>4 THE DEPONENT: Well, I didn't use</p> <p>5 defective, the word "defective" but it caused</p> <p>6 symptoms.</p> <p>7 BY MR. HUTCHINSON:</p> <p>8 Q. And, Doctor, it was your opinion in</p> <p>9 the White case that the TVT product degrade, is</p> <p>10 that correct?</p> <p>11 A. I don't see any mentioning of TVT</p> <p>12 regarding degradation. Let me read the whole</p> <p>13 paragraph.</p> <p>14 Q. Doctor, it's on the last page. "It</p> <p>15 is my opinion that polypropylene of the mesh</p> <p>16 device degraded while in the body of Ms. White."</p> <p>17 Did I read that correctly?</p> <p>18 A. Well it doesn't say "TVT" anywhere.</p> <p>19 Q. Dr. Iakovlev, did I read that</p> <p>20 correctly?</p> <p>21 A. Yes, you did.</p> <p>22 Q. Thank you.</p> <p>23 A. You didn't read TVT anywhere.</p> <p>24 Q. And in fact, Doctor, you write on</p>
Page 347	Page 349
<p>1 A. I'm not stating that I received a</p> <p>2 TVT sling in my White report. I received a</p> <p>3 posterior Gynemesh and I gave my opinions</p> <p>4 regarding Gynemesh.</p> <p>5 Q. And you also gave opinions regarding</p> <p>6 the TVT sling for Ms. White didn't you, sir? In</p> <p>7 fact on page 9 under "Urinary Symptoms" you write:</p> <p>8 "Clinical records indicated</p> <p>9 worsening of urge incontinence and</p> <p>10 appearance of urinary obstruction</p> <p>11 approximately six weeks after the</p> <p>12 placement of TVT sling."</p> <p>13 Did I read that correctly?</p> <p>14 MR. FREESE: That's now the second</p> <p>15 question. You asked a question, then he didn't</p> <p>16 answer it and you've asked a second question now.</p> <p>17 Which one do you want him to answer?</p> <p>18 BY MR. HUTCHINSON:</p> <p>19 Q. Dr. Iakovlev, you also gave opinions</p> <p>20 regarding the TVT sling for Ms. White didn't you,</p> <p>21 sir?</p> <p>22 A. Yes. Regarding urinary symptoms I</p> <p>23 gave opinions. Again --</p> <p>24 Q. And in fact, Doctor, you gave</p>	<p>1 page 9 of your report for Ms. White that she did</p> <p>2 receive a TVT sling didn't you, sir?</p> <p>3 A. Well, that's what I copied from the</p> <p>4 records.</p> <p>5 Q. And, Doctor, according to the</p> <p>6 implant record Ms. White didn't receive a TVT</p> <p>7 sling did she, sir?</p> <p>8 MR. FREESE: Object to the form of the</p> <p>9 question. Unless you're going to state on the</p> <p>10 record and stipulate that there's no other medical</p> <p>11 record in Ms. White's file that describes a TVT</p> <p>12 sling -- you've taken one page out of someone's</p> <p>13 file and are attempting to, I suppose, represent</p> <p>14 that that is the only record of the description of</p> <p>15 the sling. I mean, it's totally improper. I know</p> <p>16 you've given me a standing objection on it. I</p> <p>17 think we're wasting time. I don't know how you</p> <p>18 can ever lay a foundation on this.</p> <p>19 MR. HUTCHINSON: Counsel, this has a</p> <p>20 serial number for the implant. Your objection is</p> <p>21 noted. Just make your objection, we'll move on.</p> <p>22 BY MR. HUTCHINSON:</p> <p>23 Q. Dr. Iakovlev, on Exhibit 14 this</p> <p>24 lists the two implants that Ms. White received by</p>

88 (Pages 346 to 349)

Vladimir Iakovlev, M.D.

Page 350	Page 352
<p>1 serial number, correct?</p> <p>2 A. That's correct.</p> <p>3 Q. And, Dr. Iakovlev, did Ms. White</p> <p>4 received a TVT product with a specific serial</p> <p>5 number, yes or no?</p> <p>6 A. Well all of them have specific</p> <p>7 numbers.</p> <p>8 Q. Move to strike as nonresponsive.</p> <p>9 MR. ANDERSON: He answered your</p> <p>10 question.</p> <p>11 BY MR. HUTCHINSON:</p> <p>12 Q. My question, sir, did Ms. White</p> <p>13 receive a TVT product with an Ethicon serial</p> <p>14 number, yes or no?</p> <p>15 A. I cannot tell you. I wasn't</p> <p>16 handling the product. I was not inserting them.</p> <p>17 Q. Doctor, if you look at page 14?</p> <p>18 A. But it's one page and --</p> <p>19 Q. I understand that, but my question</p> <p>20 is if you look at Exhibit 14 can you tell us, do</p> <p>21 you have Exhibit 14 in front of you, sir?</p> <p>22 A. Yes, it's in front of me.</p> <p>23 Q. Is it far enough away where you can</p> <p>24 read it?</p>	<p>1 A. Yes.</p> <p>2 Q. You have a figure set 8(E) at the</p> <p>3 bottom, do you see that?</p> <p>4 A. I do.</p> <p>5 Q. And I'm going to ask, Doctor, if</p> <p>6 you'll you use your black pen to circle that</p> <p>7 photograph, or those two photographs at the bottom</p> <p>8 please on page 60 of your Wave 1 report.</p> <p>9 A. So which ones?</p> <p>10 Q. The two photographs at the bottom on</p> <p>11 page 60 of your Wave 1 report. And, Doctor, you</p> <p>12 labelled those photographs as "bladder muscles",</p> <p>13 correct?</p> <p>14 A. Well, let's --</p> <p>15 Q. Well --</p> <p>16 A. You're stopping me. The photographs</p> <p>17 relate to specific portion of the report which is</p> <p>18 on a different page.</p> <p>19 Q. And, Doctor, my question to you is,</p> <p>20 for the photographs that you've circled on page 60</p> <p>21 you write at the bottom, "Involvement of the</p> <p>22 detrusor (bladder) muscle by the mesh, smooth</p> <p>23 muscle." Did I read that correctly, sir?</p> <p>24 A. Yes. You read it correctly but you</p>
Page 351	Page 353
<p>1 A. Well I know what it says.</p> <p>2 Q. Doctor, according to Exhibit 14 did</p> <p>3 Ms. White receive a TVT product with an Ethicon</p> <p>4 serial number, yes or no?</p> <p>5 A. On that page there is no mentioning</p> <p>6 of TV -- Ethicon TVT brand name.</p> <p>7 Q. Thank you. Doctor, I want to hand</p> <p>8 you what's been marked as Exhibit 15 to you</p> <p>9 deposition.</p> <p>10 ---DEFENSE EXHIBIT NO. 15: Expert</p> <p>11 report of Dr. Iakovlev In Re. Ethicon,</p> <p>12 Inc., Pelvic Repair System Products</p> <p>13 Liability Litigation relating to all</p> <p>14 Wave 1 Cases.</p> <p>15 BY MR. HUTCHINSON:</p> <p>16 Q. In fact this is a report that you</p> <p>17 prepared against Ethicon as early as January of</p> <p>18 this year, is that correct?</p> <p>19 A. That's correct.</p> <p>20 Q. And this is a report that's signed</p> <p>21 and dated by you. Is that correct, sir?</p> <p>22 A. That's correct.</p> <p>23 Q. And if we look at page 60 of your</p> <p>24 report.</p>	<p>1 omitted that these all photographs they belong to</p> <p>2 a specific section of the report, and that section</p> <p>3 is in front and I can guide you to that.</p> <p>4 Q. Well one of my questions, Doctor, is</p> <p>5 that is of the bladder muscle isn't it?</p> <p>6 A. The top photograph? Yes, it is</p> <p>7 bladder muscle.</p> <p>8 Q. What about the bottom photograph?</p> <p>9 A. All these photographs they combine</p> <p>10 both bladder and the rectum. And the section in</p> <p>11 the front clearly describes either bladder or</p> <p>12 rectum.</p> <p>13 Q. And, Doctor, on the photographs on</p> <p>14 the bottom of page 60 you don't describe these as</p> <p>15 rectum muscles do you?</p> <p>16 A. I describe them on a different page</p> <p>17 of this report.</p> <p>18 Q. Move to strike as nonresponsive.</p> <p>19 MR. ANDERSON: You may not like his</p> <p>20 answer but it's a responsive answer.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. My question, Doctor, is that on page</p> <p>23 60 you don't describe these muscles as rectal</p> <p>24 muscles do you, sir?</p>

89 (Pages 350 to 353)

Vladimir Iakovlev, M.D.

Page 354	Page 356
<p>1 A. I describe them on a different page 2 of this report. 3 Q. In fact, Doctor, if we look at page 4 61 of that report, the very next page, you talk 5 about -- or you show two pictures and label those 6 bladder muscles too, don't you? 7 A. Again, all these pictures they 8 represent either bladder or the rectum. And it 9 clearly -- it is clearly described in the report 10 in appropriate section of this report. 11 Q. Where does it say "rectum" on these 12 pictures that you have in front of you on page 60 13 and 61? 14 A. I keep telling you it's in a 15 different page of the report. 16 Q. Doctor, this photograph on -- strike 17 that. 18 Doctor, looking on page 60 of the 19 photograph you've circled? 20 A. Yes. 21 Q. Would you show those to the jury 22 please? 23 MR. ANDERSON: No. You can show them to 24 the jury if you want to. Here you go.</p>	<p>1 it. 2 MR. HUTCHINSON: I am going to get an 3 answer to the question and the witness may not 4 want to do it and that's fine. 5 MR. FREESE: Hold on a sec. You're not 6 asking a question he's refusing to answer, you're 7 asking him to do physical -- become a 8 demonstrative aid for you. That's not his 9 function here. He's here to answer questions 10 about his opinions. If you want the jury to see 11 something you are perfectly welcome to hold it up 12 in front of the camera and show it to them. 13 MR. ANDERSON: You're not going to 14 disrespect this expert by having him sit there 15 holding up your stuff and then yelling at him. 16 Not going to have it. We're done with it. 17 BY MR. HUTCHINSON: 18 Q. Doctor, you've held up a lot of 19 exhibits for the plaintiff lawyers haven't you, 20 sir? 21 MR. ANDERSON: We've done that. We're 22 not doing it any more. 23 MR. HUTCHINSON: No, I'm asking him -- 24 MR. ANDERSON: No, no --</p>
Page 355	Page 357
<p>1 MR. HUTCHINSON: Counsel, we're going to 2 be here all day long but I'm not going to stand in 3 front of the jury and show them the pictures. 4 MR. ANDERSON: You're not going to make 5 him do it. You bring them to trial and do it 6 yourself then. 7 BY MR. HUTCHINSON: 8 Q. Dr. Iakovlev, I've handed you what 9 is Exhibit 15. Would you take it please? 10 A. Yes. 11 Q. Dr. Iakovlev, my question is this, 12 will you agree to show the jury the photographs on 13 page 16? 14 MR. ANDERSON: No, you can put your 15 camera on it. He's not going to do this any more. 16 MR. FREESE: Why are we arguing about 17 this? Chad, just hold it up yourself. The 18 camera's right next to you. Nobody's objecting if 19 you want to hold it up. 20 MR. HUTCHINSON: I'm entitled to an 21 answer from the witness. 22 MR. ANDERSON: No, you're not. You 23 cannot bypass the lawyers to get to the witness. 24 If we tell him he's not doing it he's not doing</p>	<p>1 MR. HUTCHINSON: I'm getting an answer 2 to the question. 3 BY MR. HUTCHINSON: 4 Q. Dr. Iakovlev, you've held up 5 exhibits for the plaintiff lawyers haven't you. 6 MR. FREESE: A piece of wood, the same 7 piece of wood you asked him to hold. 8 THE DEPONENT: I think I was holding 9 only piece of wood, nothing else. 10 BY MR. HUTCHINSON: 11 Q. And, Doctor -- 12 MR. ANDERSON: Why don't you just ask 13 him a question and move on with the deposition. 14 BY MR. HUTCHINSON: 15 Q. -- would you agree to show the jury 16 the photographs on page 60? 17 MR. FREESE: No, he won't. You can show 18 the jury the photographs if you like. 19 BY MR. HUTCHINSON: 20 Q. Would you agree to do that? 21 MR. FREESE: No. I'm instructing him 22 not to do it. This is not even about the Ramirez 23 case. If you think it's relevant to something you 24 want to prove in Ramirez then you hold it up.</p>

90 (Pages 354 to 357)



Vladimir Iakovlev, M.D.

Page 358	Page 360
<p>1 He's here to answer questions about his opinion in 2 Ramirez. We don't need to go through these 3 gymnastics, Chad. If you want the jury to see the 4 picture hold it up. Hire an IT guy to put it up 5 on the screen. 6 MR. ANDERSON: I think J&amp;J can probably 7 afford it, huh? We let you use our guy. Why 8 didn't you bring something to show through there? 9 We're not going to do your work for you. Are you 10 going to ask the question or not? 11 MR. FREESE: Really, we're just wasting 12 time. Let's not argue about it. If you want to 13 hold something up hold it up but he's not your 14 demonstrative aid. 15 MR. HUTCHINSON: My question is which 16 one of you all are defending this deposition? 17 MR. FREESE: Both of us are. 18 MR. ANDERSON: Are you going to ask your 19 questions or not? This is ridiculous. 20 BY MR. HUTCHINSON: 21 Q. Dr. Iakovlev, on page 60 of your 22 report, are any of the photographs you show on 23 page 60 of your report labelled as rectal muscles? 24 Yes or no?</p>	<p>1 your expert consulting work of those related to 2 women who have been injured by mesh? 3 MR. HUTCHINSON: Objection to form, 4 foundation. 5 THE DEPONENT: Yes. 6 BY MR. ANDERSON: 7 Q. And are you asked to relate your 8 pathological findings to complications that women 9 who've been injured by AMS products, Bard 10 products, Boston Scientific, Ethicon products, is 11 that correct? 12 MR. HUTCHINSON: Objection, foundation. 13 THE DEPONENT: That's correct. 14 BY MR. ANDERSON: 15 Q. And are these related to cases that 16 are pending all across the United States? 17 A. Yes, that's correct. 18 Q. And is this all involving 19 transvaginal polypropylene meshes? 20 A. Yes. 21 Q. Like the TVT-O? 22 A. Like the TVT-O. 23 Q. And are all the meshes that you've 24 looked at still on the market?</p>
Page 359	Page 361
<p>1 A. As I said, the description of these 2 pictures is on a different page of this report. 3 Q. We'll take a quick break. 4 THE VIDEOGRAPHER: Going off the record 5 at 5:17 p.m. 6 --- Break taken. 7 THE VIDEOGRAPHER: Back on the record at 8 5:29 p.m. 9 BY MR. HUTCHINSON: 10 Q. Dr. Iakovlev, no further questions. 11 A. Thank you. 12 RE-DIRECT EXAMINATION BY MR. ANDERSON: 13 Q. Good afternoon, Dr. Iakovlev. The 14 attorney for the defendants asked you if you have 15 been retained as an expert consultant in cases 16 against the mesh manufacturers AMS, Bard, Boston 17 Scientific and Ethicon. Do you remember that? 18 A. Yes, I do. 19 Q. And for those cases that you've 20 reviewed estimate how many pages of medical 21 records of the patients that you have reviewed in 22 all those cases? 23 A. Thousands. 24 Q. Okay. And are -- is your review and</p>	<p>1 A. No, some of them were so bad that -- 2 MR. HUTCHINSON: Objection, irrelevant. 3 THE DEPONENT: -- they discontinued 4 their production. 5 MR. HUTCHINSON: Objection, relevancy. 6 BY MR. ANDERSON: 7 Q. Is your work in those cases 8 something that has formed, in addition to your 9 background, training, and experience, formed the 10 basis for you to be able to do your work in the 11 scientific literature? 12 A. Yes. 13 Q. And with regard to your publications 14 in the scientific literature regarding 15 transvaginal meshes, do you include images from 16 all different manufacturers in those scientific 17 studies? 18 A. Yes, I do. When I show a 19 histological feature I include all manufacturers. 20 I mean, the features are the same across these 21 manufacturers. 22 Q. From a pathological standpoint? 23 A. From a pathological standpoint. 24 Q. And in your review of all the</p>

91 (Pages 358 to 361)

Vladimir Iakovlev, M.D.

Page 362	Page 364
<p>1 literature in this case that we discussed quite a 2 bit in your direct examination, have you seen 3 where other scientists, including pathologists, 4 have included features of mesh from different 5 manufactures in their scientific work? 6 A. That's correct. Sometimes they 7 don't even know who the manufacturer is. And 8 polypropylene mesh they describe the mesh but 9 manufacturer isn't known. 10 Q. Do you find that uncommon or 11 inappropriate to include features of different 12 mesh manufacturers in a body of mesh research in 13 order to try to relate pathological findings to 14 clinical complications? 15 MR. HUTCHINSON: Objection foundation. 16 Counsel, you're talking about mesh from other 17 manufacturers that he used? 18 MR. FREESE: Yeah, something like you 19 did in the last hour. 20 MR. ANDERSON: Yeah, something like 21 that. 22 BY MR. ANDERSON: 23 Q. Go ahead and answer it please. 24 A. Yes. I think it is appropriate just</p>	<p>1 MR. HUTCHINSON: Move to strike as 2 nonresponsive. 3 BY MR. ANDERSON: 4 Q. When you have prepared reports in 5 these cases where women have been injured by 6 various mesh manufacturers have you prepared 7 general reports as well as case-specific reports? 8 MR. HUTCHINSON: Objection, relevance. 9 THE DEPONENT: Yes, I did. 10 BY MR. ANDERSON: 11 Q. And in the general portion of those 12 reports are those the one that counsel went to 13 great lengths to show you one after another after 14 another at the end of your cross-examination? 15 A. Yes. 16 Q. And in those general reports, like 17 your scientific literature, do you include futures 18 from all different mesh manufacturers that you see 19 in pathological findings? 20 A. Yes, always. 21 Q. And do you find anything 22 inappropriate or uncommon about showing 23 pathological changes across all different types of 24 mesh manufacturers in your general reports that</p>
Page 363	Page 365
<p>1 to see the range of changes and see if there is 2 any change, any difference. In fact most of the 3 time I cannot even tell what is manufacturer. 4 Looking at the histological slides they all look 5 the same. The only difference is some of them 6 have blue fibres and some of them have only clear 7 fibers. 8 Q. Counsel was asking you questions 9 about the testimony against these mesh 10 manufacturers, approximately how many women does 11 that represent that you have -- that have made 12 claims for injuries regarding mesh that you have 13 performed expert consulting work for? 14 MR. HUTCHINSON: Objection, foundation. 15 BY MR. ANDERSON: 16 Q. How many are we talking about, 17 doctor? 18 A. Thousands. 19 MR. HUTCHINSON: Same objection, 20 foundation. 21 THE DEPONENT: Tens of thousands of 22 women were injured. And as I said, some of the 23 devices have been taken off the market because of 24 high complication rate.</p>	<p>1 you prepared in this litigation? 2 MR. HUTCHINSON: Objection, foundation. 3 THE DEPONENT: No, it's not 4 inappropriate. Sometimes it's even my purpose 5 just to show the similarities, how similar they 6 are under the microscope. 7 BY MR. ANDERSON: 8 Q. So for all those reports he kept 9 showing you one after another and showing this 10 image versus that image, was it your intent to 11 present pathological findings across the mesh 12 manufacturers? 13 MR. HUTCHINSON: Objection, foundation. 14 THE DEPONENT: Yes, it was. My intent 15 was to show features and they were similar between 16 manufacturers because the designs are similar. 17 BY MR. ANDERSON: 18 Q. Of the polypropylene meshes? 19 A. The polypropylene meshes and 20 transvaginal devices made out of polypropylene 21 meshes. 22 Q. One of the things counsel showed you 23 was -- I don't know, Exhibit 12 or something. But 24 he was showing you this bark implying that there</p>

Vladimir Iakovlev, M.D.

Page 366	Page 368
<p>1 was something inappropriate about putting in 2 broken bark from one manufacturer to another. Do 3 you see that page? 4 MR. HUTCHINSON: Objection. 5 THE DEPONENT: Yes, I do. 6 MR. HUTCHINSON: Objection, form. 7 BY MR. ANDERSON: 8 Q. What's it say in the description of 9 that? 10 A. "Blue granules in a bark separated 11 from the core. Transvaginal mesh of another 12 manufacturer." 13 Q. Thank you. When you were shown the 14 information on the Virginia White case, do you 15 remember that? 16 A. Yes. 17 Q. Does Virginia White's case have 18 anything to do with Ms. Ramirez? 19 MR. HUTCHINSON: Counsel, I'm just going 20 to object to the extent that we've admitted that 21 exhibit for the limited purpose of attacking his 22 credibility, and that does not make the entire 23 Virginia White case relevant. 24 MR. FREESE: Well we'll see about that.</p>	<p>1 MR. ANDERSON: I already have and I will 2 again. 3 MR. HUTCHINSON: Don't raise -- 4 MR. ANDERSON: You do not talk about 5 sloppy about this gentleman, you understand? 6 MR. HUTCHINSON: Don't raise your voice 7 at me. 8 MR. ANDERSON: You will treat him with 9 respect. 10 MR. HUTCHINSON: I'm treating him with 11 respect. 12 MR. ANDERSON: You talk about sloppy, 13 talk about your client who's sloppy. 14 MR. HUTCHINSON: You treat everybody 15 else here with respect, counsel. Don't you raise 16 your voice at me. 17 MR. ANDERSON: I already have and I will 18 again if you keep talking about my witness like 19 that. 20 MR. HUTCHINSON: I'm not talking about 21 your witness. 22 MR. ANDERSON: How about your sloppy 23 manufacturer? 24 MR. HUTCHINSON: I'm not talking about</p>
Page 367	Page 369
<p>1 I mean my response to that, Chad, is, you know, 2 there's a reason the rules of evidence don't allow 3 for impeachment on collateral matters, because 4 then you get off into a mini-trial on something 5 else. You deliberately brought one page of a 6 medical record of a file that I'm certain has 7 hundreds of pages of medical records and then 8 tried to imply -- or not imply, basically said 9 that he mistranscribed that medical record into 10 his report. So you have put that into evidence. 11 MR. HUTCHINSON: Fair enough. But, 12 counsel, we're simply showing his sloppy 13 methodology. You know it's sloppy and we put it 14 in for the limited purpose of attacking his 15 credibility. 16 MR. ANDERSON: I take great exception -- 17 MR. HUTCHINSON: So note my objection. 18 MR. ANDERSON: No, no, no. No. You 19 keep your personal attacks to yourself. 20 MR. HUTCHINSON: Hey -- 21 MR. ANDERSON: You want to talk about 22 sloppy? 23 MR. HUTCHINSON: Don't raise your voice 24 at me.</p>	<p>1 your witness. 2 MR. FREESE: Just object to the form and 3 let us ask -- you introduced this, Chad. We're 4 going to do a redirect on what you introduced and 5 you can object to the form of the question. 6 MR. HUTCHINSON: I've already lodged my 7 objection, counsel. Thank you. 8 BY MR. ANDERSON: 9 Q. Doctor, is Ms. White a different 10 plaintiff than Ms. Ramirez? 11 A. Yes, she is. 12 Q. Is her case pending in a different 13 court? 14 A. Yes, it is. 15 Q. How many page of Ms. White's -- 16 MR. HUTCHINSON: Can we have a standing 17 objection to relevance. 18 MR. ANDERSON: You can have a standing 19 objection to everything you want. 20 MR. FREESE: Absolutely. You can have a 21 standing objection on relevancy. 22 MR. HUTCHINSON: Well, what I mean 23 standing objection on relevancy I'm talking about 24 admitting the exhibit for the limited purpose of</p>

Vladimir Iakovlev, M.D.

Page 370	Page 372
<p>1 attacking his credibility.  2 MR. ANDERSON: Or trying to attack it.  3 MR. FREESE: You can have it.  4 BY MR. ANDERSON:  5 Q. How many pages of Ms. White's  6 medical record did the defense lawyer show you?  7 A. Nothing, just one page.  8 Q. How many medical records were in  9 Ms. White's --  10 A. Sometimes there are thousands of  11 pages.  12 Q. Did counsel in fairness provide you  13 with those medical records to take a look at?  14 A. No, he didn't.  15 Q. Did he -- he kept saying that you  16 gave opinion in this case, did he offer up your  17 testimony for you to take a look at?  18 A. No, he didn't.  19 Q. Doctor, he was -- during this part  20 of your questioning he was asked (sic) whether or  21 not TVT is made by Ethicon, do you recall that?  22 A. Yes, I do.  23 Q. In your review of the thousands of  24 pages of medical records across all mesh</p>	<p>1 Q. From all those reports that counsel  2 kept showing you one after another were there any  3 mixed up samples in any of that?  4 A. No.  5 Q. When you prepare a medical  6 chronology in your case-specific reports are you  7 simply transferring the patient's medical records  8 and what her doctors have said into your own  9 chronology?  10 A. Yes.  11 Q. When you're doing your research or  12 you're preparing the general portion of your  13 reports do you even care which mesh manufacturer  14 it is when you're trying to show the pathological  15 findings and the tissue changes that can relate in  16 a woman's tissue to mesh?  17 A. No.  18 Q. Why is that?  19 A. Because, as I said, they all behave  20 the same way. TVT slings and tapes are identical.  21 The only difference is AMS was making them out of  22 all clear fiber, Boston Scientific and Ethicon  23 slings are indistinguishable under microscope. I  24 wouldn't be able to tell you which one is which.</p>
Page 371	Page 373
<p>1 manufacturers, have you noted that TVT can be used  2 interchangeably from one mesh manufacturer to  3 another.  4 MR. HUTCHINSON: Objection, leading.  5 THE DEPONENT: That's what I told him.  6 When I was answering his questions my first answer  7 was that TVT is a loose term used by clinicians.  8 It means just a sling.  9 BY MR. ANDERSON:  10 Q. What does "TVT" stand for?  11 A. Transvaginal tape.  12 Q. And was Ms. White implanted with a  13 Boston Scientific transvaginal tape?  14 A. Well, she was implanted with some  15 type of transvaginal tape.  16 Q. And was it retropubic?  17 A. Apparently it was retropubic, but I  18 would have to go through the records again to tell  19 you exactly.  20 Q. And did counsel allow you an  21 opportunity to look through and see where the list  22 -- the "Ethicon TVT retropubic" was in her  23 records?  24 A. No, he didn't.</p>	<p>1 Q. The defendant for J&amp;J -- the defense  2 counsel for J&amp;J pointed out in this report,  3 Exhibit 15, rectal muscle and bladder muscle. Do  4 you have that in front of you?  5 A. Yes, I do.  6 Q. And do you see on page 58 where you  7 have listed there "rectal muscle"?  8 A. Yes.  9 Q. And 59, "bladder muscle" et cetera?  10 A. Yes, I do.  11 Q. If you turn back to your report on  12 page 17?  13 A. Yes.  14 Q. Do you recall during your testimony  15 you kept saying that there was a part of your  16 report that that all related to?  17 A. Yes.  18 Q. Did counsel give you an opportunity  19 to point that out to the jury?  20 A. No. After my repeated requests he  21 didn't give me that opportunity.  22 Q. I'll give you that opportunity now.  23 If you can look at page 17 please explain to the  24 jury what was going on with those images and how</p>

94 (Pages 370 to 373)

Vladimir Iakovlev, M.D.

Page 374	Page 376
<p>1 you referred to it in your report?</p> <p>2 A. All those images were provided to</p> <p>3 support one paragraph on page 17 which has heading</p> <p>4 "Involvement of Smooth Muscle of the Vaginal Wall,</p> <p>5 Urinary Bladder, Urethra and Rectum". And then</p> <p>6 the description is:</p> <p>7 "In explanting transvaginal mesh</p> <p>8 devices the smooth muscle of the pelvic</p> <p>9 organs can become affected by the mesh.</p> <p>10 Microphotographs in figure set 8 are</p> <p>11 representative of the presence of</p> <p>12 smooth muscle in explanted mesh</p> <p>13 devices."</p> <p>14 And then all of those images they all</p> <p>15 show the same feature, presence of smooth muscle</p> <p>16 within the mesh. Doesn't matter which organ.</p> <p>17 Q. Okay. Let's shift gears for a</p> <p>18 minute. During cross-exam counsel emphatically</p> <p>19 asked you things that you don't do. You don't</p> <p>20 implant mesh, right?</p> <p>21 A. Yes.</p> <p>22 Q. You don't explant mesh?</p> <p>23 A. Yes.</p> <p>24 Q. You're not an astronaut are you?</p>	<p>1 pathological findings and to be able to express</p> <p>2 your opinions that you've given here today?</p> <p>3 MR. HUTCHINSON: Objection leading, also</p> <p>4 form.</p> <p>5 THE DEPONENT: No. None of that is</p> <p>6 taught in pathology residency, and we're using</p> <p>7 completely different tools and I'm trained in</p> <p>8 completely different methods. None of the</p> <p>9 pathologists have expertise in any of those</p> <p>10 techniques.</p> <p>11 MR. HUTCHINSON: Objection. Move to</p> <p>12 strike as nonresponsive.</p> <p>13 BY MR. ANDERSON:</p> <p>14 Q. Do pathologists typically have an</p> <p>15 expertise or experience in molecular weight, FTIR,</p> <p>16 tensile strength, bench-top testing, elongation or</p> <p>17 toughness testing?</p> <p>18 A. I think none of the pathologists</p> <p>19 anywhere in the world have knowledge of all those</p> <p>20 techniques.</p> <p>21 Q. And do pathologists around the</p> <p>22 world, when they are looking at explanted meshes,</p> <p>23 need FTIR, or tensile strength, or molecular</p> <p>24 weight testing in order to arrive at</p>
Page 375	Page 377
<p>1 A. No.</p> <p>2 MR. HUTCHINSON: Objection,</p> <p>3 argumentative.</p> <p>4 Counsel, counsel, withdraw that</p> <p>5 question, please. Counsel, Ben, would you</p> <p>6 withdraw the question please? It's argumentative.</p> <p>7 Will you withdraw it?</p> <p>8 MR. ANDERSON: No.</p> <p>9 BY MR. ANDERSON:</p> <p>10 Q. Let me ask you this, Dr. Iakovlev,</p> <p>11 do urogynecologist typically look at pathology?</p> <p>12 A. No.</p> <p>13 Q. Do polymer scientists typically look</p> <p>14 at pathology?</p> <p>15 A. I hope not.</p> <p>16 Q. So within different fields are there</p> <p>17 different tools for each specialty to be able to</p> <p>18 examine patients and to be able to examine samples</p> <p>19 that come from patients?</p> <p>20 A. That's correct.</p> <p>21 Q. So despite the fact that you don't</p> <p>22 do this long list, FTIR, SEM, tensile strength,</p> <p>23 elongation and toughness, or bench-top testing, do</p> <p>24 you need to do any of that in order to arrive at</p>	<p>1 clinico-pathological correlations?</p> <p>2 A. No, they don't.</p> <p>3 Q. Counsel asked you questions as to</p> <p>4 whether or not you ruled out vaginal infections,</p> <p>5 pre-existing pelvic pain, pre-existing</p> <p>6 dyspareunia, some metal in the Essure device, and</p> <p>7 other exams that Ms. Ramirez had. Do you recall</p> <p>8 that part of your questioning?</p> <p>9 MR. HUTCHINSON: Objection, compound.</p> <p>10 Also object to form and foundation.</p> <p>11 BY MR. ANDERSON:</p> <p>12 Q. Whatever. Go ahead, Doctor.</p> <p>13 A. I do.</p> <p>14 Q. Did any of the doctors for</p> <p>15 Ms. Ramirez list as the reason for her 2010 or</p> <p>16 2015 explants vaginal infections?</p> <p>17 A. No.</p> <p>18 Q. Did any of the doctors who explanted</p> <p>19 her TVF Ethicon mesh in 2010 or 2015 list</p> <p>20 pre-existing dyspareunia as the reason for it?</p> <p>21 A. No.</p> <p>22 Q. Did any of them list the Essure</p> <p>23 device or some sort of metallic foreign body</p> <p>24 reaction as the reason that they explanted her TVT</p>



Vladimir Iakovlev, M.D.

Page 378	Page 380
<p>1 sling in 2010 or 2015?</p> <p>2 A. No, they explanted TVT sling.</p> <p>3 Q. Do you need to know the name of the</p> <p>4 doctor who explanted the TVT-O device, or who</p> <p>5 implanted the TVT-O device, in order to arrive at</p> <p>6 pathological conclusions and to give the jury</p> <p>7 opinions on what you see on the microscopic</p> <p>8 slides?</p> <p>9 A. No, I don't need it.</p> <p>10 Q. Do you need to know the name of your</p> <p>11 technician in your path lab who may have processed</p> <p>12 the slides in order to offer opinions as an expert</p> <p>13 in the field of pathology for the jury here today?</p> <p>14 A. No, I don't need it.</p> <p>15 Q. Can you put up Exhibit 4(C)?</p> <p>16 Doctor, showing you the -- Doctor, redirecting you</p> <p>17 back to the part of your testimony where you were</p> <p>18 talking about Ms. Ramirez's slides here, and the</p> <p>19 S100 staining on the left showing the nerve</p> <p>20 entrapment and the scarring on the right. Do you</p> <p>21 recall that part of your testimony?</p> <p>22 A. I do.</p> <p>23 Q. Do you need to count the nerve</p> <p>24 density in order to make the opinions that you do</p>	<p>1 to the explants from Ms. Ramirez's body?</p> <p>2 A. No. I could see these nerves even</p> <p>3 on H&amp;E. I didn't even need to do S100.</p> <p>4 MR. HUTCHINSON: Move to strike as</p> <p>5 nonresponsive.</p> <p>6 BY MR. ANDERSON:</p> <p>7 Q. Did you need to see this -- explain</p> <p>8 what you mean by the last statement.</p> <p>9 MR. HUTCHINSON: Also object to the</p> <p>10 form.</p> <p>11 THE DEPONENT: I can see the nerves in</p> <p>12 H&amp;E stain. And S100 was done more for</p> <p>13 demonstration, for other people to be able to see</p> <p>14 them easier, for those who are not pathologists.</p> <p>15 BY MR. ANDERSON:</p> <p>16 Q. Is the lack of dead tissue or</p> <p>17 necrosis significant to your opinions at all in</p> <p>18 this case?</p> <p>19 A. No, I don't think I barely ever</p> <p>20 describe necrosis in mesh specimens.</p> <p>21 Q. Do you need a neuroma in a pathology</p> <p>22 slide in order to diagnose whether an entrapped</p> <p>23 nerve can cause pain?</p> <p>24 A. No. I mean, I know that it can</p>
Page 379	Page 381
<p>1 regarding entrapped nerves causing pain and scar</p> <p>2 tissue leading to pain?</p> <p>3 MR. HUTCHINSON: Objection, foundation.</p> <p>4 THE DEPONENT: No, I don't need and I</p> <p>5 told it to the defense counsel.</p> <p>6 MR. HUTCHINSON: Move to strike as</p> <p>7 unresponsive.</p> <p>8 BY MR. ANDERSON:</p> <p>9 Q. Do you need to consult with a</p> <p>10 neuropathologist or any of her treating -- Ms.</p> <p>11 Ramirez's treating doctors in order to make a</p> <p>12 determination and have an opinions regarding those</p> <p>13 slides?</p> <p>14 A. No. I don't need to consult</p> <p>15 neuropathologist -- and I don't think that</p> <p>16 neuropathologist would argue that they're not</p> <p>17 nerves. They are nerves.</p> <p>18 MR. HUTCHINSON: Move to strike as</p> <p>19 nonresponsive.</p> <p>20 BY MR. ANDERSON:</p> <p>21 Q. Do you need, what did defense</p> <p>22 counsel say? Nociceptors and PGP9.5 in order to</p> <p>23 be able to make the opinions you do about the</p> <p>24 images that the jury is seeing there with regard</p>	<p>1 happen. And we can see nerves here right there on</p> <p>2 the screen.</p> <p>3 Q. Counsel went to great lengths to</p> <p>4 talk about formalin, alcohol, xylene, he said</p> <p>5 toluene, it's toluene. Do you remember the</p> <p>6 questions about that?</p> <p>7 A. Yes, I do.</p> <p>8 MR. HUTCHINSON: Objection,</p> <p>9 argumentative. Counsel, did you hear my</p> <p>10 objection?</p> <p>11 MR. ANDERSON: What did you say?</p> <p>12 MR. HUTCHINSON: I said objection,</p> <p>13 argumentative.</p> <p>14 BY MR. ANDERSON:</p> <p>15 Q. That's fine.</p> <p>16 In terms of counsel's questions</p> <p>17 regarding the process of slides, he listed</p> <p>18 formalin, alcohol, xylene and toluene as things</p> <p>19 that are treated -- as chemicals that are used to</p> <p>20 treat specimens in order to put them on the</p> <p>21 slides. Do you recall that?</p> <p>22 A. I do.</p> <p>23 Q. Is that process of using formalin,</p> <p>24 alcohol, xylene and toluene used every day</p>

Vladimir Iakovlev, M.D.

Page 382	Page 384
<p>1 around the world to process pathological slides?</p> <p>2 A. Yes. And it is the same process and</p> <p>3 it's been used for decades, for a hundred years.</p> <p>4 Q. And over those hundred years, or</p> <p>5 actually let's just take the last 30, has any</p> <p>6 scientific literature, or have you noticed from</p> <p>7 your own examination of explants that alcohol,</p> <p>8 xylene, toluene, or any other treatment of the</p> <p>9 sample before it's put on the slide, has any</p> <p>10 effect in causing you to be able to -- whether you</p> <p>11 can render opinions as to whether or not the mesh</p> <p>12 has certain tissue reaction in the woman's tissue?</p> <p>13 MR. HUTCHINSON: Objection, foundation.</p> <p>14 THE DEPONENT: It was a long question.</p> <p>15 Can you repeat it?</p> <p>16 MR. HUTCHINSON: Ben, can you rephrase</p> <p>17 that question for us please.</p> <p>18 MR. ANDERSON: I'm going to.</p> <p>19 BY MR. ANDERSON:</p> <p>20 Q. In the hundreds of slides -- strike</p> <p>21 that.</p> <p>22 In the hundreds of explants that you've</p> <p>23 examined for purposes of your scientific work, and</p> <p>24 in the context of litigation, has the use of the</p>	<p>1 Q. And he said they don't list</p> <p>2 degradation do they? Do you remember that?</p> <p>3 A. Yes, I do.</p> <p>4 Q. Do you know if the pathologist was</p> <p>5 asked to determine whether or not there was</p> <p>6 degradation?</p> <p>7 MR. HUTCHINSON: Objection, foundation,</p> <p>8 also calls for speculation.</p> <p>9 THE DEPONENT: What I see -- what I saw</p> <p>10 in the report the only question he was asked to</p> <p>11 confirm if there is mesh or not.</p> <p>12 BY MR. ANDERSON:</p> <p>13 Q. Did counsel provide you with any</p> <p>14 evidence that there was any question by the</p> <p>15 surgeon asking the pathologist there to tell him</p> <p>16 whether or not there was degradation of the mesh?</p> <p>17 Did he provide you any evidence of that?</p> <p>18 A. No.</p> <p>19 Q. Did he provide you any evidence that</p> <p>20 the surgeon asked the pathologist to tell him</p> <p>21 whether or not there was bridging fibrosis or scar</p> <p>22 plating?</p> <p>23 A. No.</p> <p>24 MR. HUTCHINSON: I'm sorry, our iPad has</p>
Page 383	Page 385
<p>1 standards of formalin, alcohol, xylene or</p> <p>2 toluene ever impacted your ability to offer</p> <p>3 opinions and to do a pathological analysis</p> <p>4 regarding what you see in the slides?</p> <p>5 MR. HUTCHINSON: Objection, foundation.</p> <p>6 THE DEPONENT: No. As I said, it's a</p> <p>7 standard technique used in all labs around the</p> <p>8 world in North America. That's how we do it.</p> <p>9 BY MR. ANDERSON:</p> <p>10 Q. Have you ever seen any of the</p> <p>11 scientific literature regarding the analysis of</p> <p>12 explanted meshes that formalin, alcohol, xylene or</p> <p>13 toluene have impacted a pathologist's ability to</p> <p>14 analyze explanted pathological tissue?</p> <p>15 A. No.</p> <p>16 Q. I mean, that's the only way to do it</p> <p>17 to use all those chemicals.</p> <p>18 MR. HUTCHINSON: Move to strike as</p> <p>19 nonresponsive.</p> <p>20 BY MR. ANDERSON:</p> <p>21 Q. You were shown the pathology report</p> <p>22 from University of Texas Southwestern from March</p> <p>23 10, 2015, by counsel. Do you recall that?</p> <p>24 A. I do.</p>	<p>1 stopped.</p> <p>2 THE VIDEOGRAPHER: Going off the record</p> <p>3 at 5:52 p.m.</p> <p>4 --- Break taken.</p> <p>5 THE VIDEOGRAPHER: Back on the record at</p> <p>6 5:53 p.m.</p> <p>7 BY MR. ANDERSON:</p> <p>8 Q. Did counsel provide you any evidence</p> <p>9 that the surgeon at University of Texas Southwest</p> <p>10 Hospital asked for any information other than that</p> <p>11 which was given in his pathology report?</p> <p>12 A. No.</p> <p>13 Q. Did counsel provide you with any</p> <p>14 evidence as to whether or not the pathologist at</p> <p>15 UT Southwestern is even aware of the pathological</p> <p>16 change in the tissue related to mesh that can lead</p> <p>17 to degradation, fibrotic bridging or scar plating?</p> <p>18 Did he provide you any evidence of that?</p> <p>19 A. No.</p> <p>20 Q. Do we have any idea what the level</p> <p>21 of knowledge or the scientific background is of</p> <p>22 the pathologist who looked at Ms. Ramirez's</p> <p>23 explant?</p> <p>24 A. We don't.</p>

Vladimir Iakovlev, M.D.

Page 386	Page 388
<p>1 MR. HUTCHINSON: Ben, I'm going to 2 object to your last question as pure speculation. 3 MR. ANDERSON: I wish you would. 4 MR. HUTCHINSON: Thank you. 5 MR. ANDERSON: Sure. 6 BY MR. ANDERSON: 7 Q. Counsel asked you a long series of 8 questions about negatively charged ions, 9 positively charged ions, hydrostatic, soluble and 10 all things like that. Do you remember that part 11 of your question? 12 A. I do. 13 Q. Are any of those features important 14 or significant to you as a pathologist in being 15 able to stain mesh explants, and to offer opinions 16 regarding what those tissue changes are on the 17 microscopic slide? 18 MR. HUTCHINSON: Objection, compound 19 question. 20 THE DEPONENT: No, doesn't matter how it 21 stains. The fact that it stains it allows me to 22 see it under microscope that's what's important. 23 Exact mechanism doesn't matter. And for many dyes 24 we don't even know exact mechanism.</p>	<p>1 not their experts in litigation but by their 2 scientists, indicating they had trouble 3 determining whether or not there was in vivo 4 degradation of their Prolene sutures because they 5 couldn't dye it properly or stain it properly? 6 MR. HUTCHINSON: Objection, 7 argumentative. 8 BY MR. ANDERSON: 9 Q. Seen any reports by them? 10 MR. HUTCHINSON: Same objection. 11 THE DEPONENT: No. They used phloxine 12 and it readily stained the degraded layer. 13 BY MR. ANDERSON: 14 Q. I'm going to direct your attention 15 back to Exhibit 20, which was your publication, 16 Degradation of Polypropylene In Vivo. Do you 17 remember counsel asked you some questions about 18 that? 19 A. Yes, I do. 20 Q. Do you remember out of these 1, 2, 21 3, 4, oh, 12 or 15 page report remember him 22 pulling out two sentence for you to look at? 23 A. I do. 24 Q. And let's look at the two sentences.</p>
Page 387	Page 389
<p>1 BY MR. ANDERSON: 2 Q. How many different types of dyes or 3 staining have been used between you, other 4 pathological researchers, as well as Ethicon's own 5 internal pathologists in order to look at bark -- 6 or in order to determine whether or not -- let me 7 ask a better question. 8 How many different types of staining 9 have been used between yourself and the 10 researchers at Ethicon, based upon the internal 11 studies that you saw with regard to being able to 12 stain explanted mesh in order to see if there was 13 in vivo degradation? 14 A. At least six. 15 Q. What are those different six stains? 16 A. Hematoxylin eosin stains it, red 17 counterstain for von Kossa stains it, trichromes, 18 both masson trichrome and other trichromes stain 19 it, counterstain for immunostains stain it, 20 phloxine stains it and stained it when they used 21 in Ethicon, and I'm sure that any other stain will 22 stain in. 23 Q. Have you been shown by counsel any 24 internal Ethicon documents by their scientists,</p>	<p>1 Under the abstract, "The fundamental question as 2 to whether polypropylene degrades in vivo is still 3 debated." Do you remember that? 4 A. I do. 5 Q. And then, "The causes and mechanisms 6 of complications associated with the mesh remain 7 incompletely understood." Do you see that? 8 A. Yes, I do. 9 Q. What did that mean in the context of 10 your study? 11 A. It means that although there were 12 studies showing it there were attempts to 13 discredit those studies. 14 Q. Okay. 15 A. And I used different method to show 16 again the same feature, but using histological 17 methods, which shows some other features of 18 degradation which were not shown before, but they 19 show exactly is the same mechanism in the hope 20 that finally, after this, maybe everybody will 21 agree that it does degrade. I mean there will be 22 no further attempts to dispute those findings. 23 Q. And if in fact there is a debate do 24 you recall the slides that we put up with all of</p>

98 (Pages 386 to 389)

Vladimir Iakovlev, M.D.

Page 390	Page 392
<p>1 the various authors, and I showed you all of the</p> <p>2 various scientific literature regarding</p> <p>3 polypropylene degradation. Do you recall that?</p> <p>4 A. I do.</p> <p>5 MR. HUTCHINSON: Objection. Foundation.</p> <p>6 BY MR. ANDERSON:</p> <p>7 Q. Any question in your mind that there</p> <p>8 was any debate by those scientists as to whether</p> <p>9 or not polypropylene degrades in the body?</p> <p>10 A. No.</p> <p>11 MR. HUTCHINSON: Objection, also</p> <p>12 speculation.</p> <p>13 BY MR. ANDERSON:</p> <p>14 Q. Go ahead.</p> <p>15 A. It was mostly from a small group of</p> <p>16 people who were questioning the findings, but I</p> <p>17 did not see actually studies by them showing that</p> <p>18 it is not degraded polypropylene. The only thing</p> <p>19 they did they questioned the results of those</p> <p>20 studies but they never proved that it's not</p> <p>21 polypropylene.</p> <p>22 Q. And was this Exhibit 20 actually a</p> <p>23 study rather than just a criticism of other</p> <p>24 people's studies?</p>	<p>1 tissue reaction." Do you recall that?</p> <p>2 A. I do.</p> <p>3 Q. This article was written in 1998?</p> <p>4 A. Yes.</p> <p>5 Q. Had transvaginal meshes even gone on</p> <p>6 the market by 1998?</p> <p>7 A. No, I don't think so.</p> <p>8 Q. And has the marketing and sales of</p> <p>9 transvaginal meshes been from 1998 to the present?</p> <p>10 A. Yes.</p> <p>11 Q. Okay.</p> <p>12 A. Within that timeframe.</p> <p>13 Q. And have -- based upon your review</p> <p>14 of the literature have you noted whether or not</p> <p>15 complications have been reported or not reported</p> <p>16 over those last 18 years?</p> <p>17 A. They have been reported over those</p> <p>18 years.</p> <p>19 Q. And what was the conclusion on page</p> <p>20 205 from the study? Let me take you down under</p> <p>21 the last part of that paragraph. Beginning with</p> <p>22 the word "visual evidence" what does that say?</p> <p>23 A. "Visual evidence of surface</p> <p>24 degradation was observed after one and</p>
Page 391	Page 393
<p>1 A. Yes, it is study.</p> <p>2 Q. And what were the results of this</p> <p>3 study regarding in vivo degradation of meshes</p> <p>4 explanted from patients?</p> <p>5 A. This study was based on 183</p> <p>6 specimens, as I remember. And it showed that in</p> <p>7 all except one or two I believe the degradation</p> <p>8 bark was detectable by histology. The only time,</p> <p>9 or in one or two sample it was not detectable</p> <p>10 because the explants were taken out of the body</p> <p>11 too early. The bark was too thin to be visible.</p> <p>12 Q. Counsel also showed you Exhibit 8,</p> <p>13 that's the Celine Mary article.</p> <p>14 A. Yes.</p> <p>15 Q. And he pulled one sentence out of</p> <p>16 this study regarding the degradation of Prolene</p> <p>17 sutures. Do you recall that?</p> <p>18 MR. HUTCHINSON: Objection,</p> <p>19 argumentative.</p> <p>20 THE DEPONENT: I do.</p> <p>21 BY MR. ANDERSON:</p> <p>22 Q. And that one sentence on that first</p> <p>23 page it says, "It has high flexibility and tensile</p> <p>24 strength and exhibits low thrombogenicity and</p>	<p>1 two years for the polypropylene but not</p> <p>2 the PVDF sutures. This stress cracking</p> <p>3 phenomenon is believed to be associated</p> <p>4 with distinct, two-phase structure of</p> <p>5 oriented polypropylene monofilaments."</p> <p>6 Q. So what does that collusion mean</p> <p>7 to -- in laypeople's terms?</p> <p>8 A. It means that polypropylene degrade,</p> <p>9 PVDF didn't degrade.</p> <p>10 Q. Counsel also pointed out the Leibert</p> <p>11 article from 1976 and asked you some questions</p> <p>12 about that. Do you recall that?</p> <p>13 MR. HUTCHINSON: Excuse me,</p> <p>14 mischaracterized the testimony. Counsel, I didn't</p> <p>15 point that article out you did.</p> <p>16 BY MR. ANDERSON:</p> <p>17 Q. In your questioning you did.</p> <p>18 A. Yes, I remember that.</p> <p>19 Q. Just turn back to page 950 where</p> <p>20 counsel was pointing out some of the conclusions.</p> <p>21 You see that?</p> <p>22 A. Yes, I do.</p> <p>23 Q. Do you see photograph 4.</p> <p>24 A. Number 4?</p>

99 (Pages 390 to 393)

Vladimir Iakovlev, M.D.

Page 394	Page 396
<p>1 Q. Do you see that?</p> <p>2 A. Yes, I do.</p> <p>3 Q. Where it says that the filaments</p> <p>4 were analyzed 30 days after implant and up to 150</p> <p>5 days? Do you see that?</p> <p>6 A. I do.</p> <p>7 Q. So between a month and five months.</p> <p>8 Do you see that?</p> <p>9 MR. HUTCHINSON: Objection, leading.</p> <p>10 MR. ANDERSON: I'm directing him to a</p> <p>11 part of the literature. Cheese and crow.</p> <p>12 BY MR. ANDERSON:</p> <p>13 Q. Do you see that?</p> <p>14 A. Yes, I do.</p> <p>15 Q. What was degradation -- strike that.</p> <p>16 Based upon the research that you've done</p> <p>17 in your analysis of over 300 explanted meshes,</p> <p>18 when does degradation become visible after it's</p> <p>19 been explanted -- implanted the human body?</p> <p>20 MR. HUTCHINSON: Objection, foundation.</p> <p>21 THE DEPONENT: About a year.</p> <p>22 BY MR. ANDERSON:</p> <p>23 Q. And this study didn't go out to a</p> <p>24 year did it?</p>	<p>1 Q. How often do pathologists examine</p> <p>2 patients in a clinical setting when they are</p> <p>3 looking at their pathology in order to determine</p> <p>4 what the tissue reactions may be in her body?</p> <p>5 A. Very rarely. Almost never.</p> <p>6 Q. Counsel showed you some comics or</p> <p>7 animations, graphics of a pelvis and wanted you</p> <p>8 point out for the jury where Ms. Ramirez had pain.</p> <p>9 Do you remember that?</p> <p>10 MR. HUTCHINSON: Objection,</p> <p>11 argumentative.</p> <p>12 THE DEPONENT: I do.</p> <p>13 BY MR. ANDERSON:</p> <p>14 Q. In forming your opinions as to</p> <p>15 whether or not the pathological changes in</p> <p>16 Ms. Ramirez's tissue correlated to the symptoms of</p> <p>17 pain in her records, did you rely on animations or</p> <p>18 did you rely on something else?</p> <p>19 A. Well, I relied on real clinical</p> <p>20 history, real records and real specimen.</p> <p>21 Q. Did you feel the need to go to</p> <p>22 Google and look up any animations of the human</p> <p>23 pelvis?</p> <p>24 A. No.</p>
Page 395	Page 397
<p>1 A. No, it didn't.</p> <p>2 Q. It didn't go beyond five months did</p> <p>3 it?</p> <p>4 MR. HUTCHINSON: Objection, leading.</p> <p>5 BY MR. ANDERSON:</p> <p>6 Q. Did it go beyond five months?</p> <p>7 A. No, it didn't.</p> <p>8 Q. Doctor, you were asked a number of</p> <p>9 questions by defense counsel as to whether or not</p> <p>10 you've ever met Ms. Ramirez. Do you remember</p> <p>11 that?</p> <p>12 A. I do.</p> <p>13 Q. How often do pathologists ever meet</p> <p>14 the patients for the pathological specimens that</p> <p>15 they're looking at?</p> <p>16 A. Practically never, I mean unless</p> <p>17 it's an autopsy case.</p> <p>18 Q. How many pathological specimens do</p> <p>19 you analyze on an annual basis?</p> <p>20 A. Sometimes up to 5,000.</p> <p>21 Q. Five thousand. Would you be able to</p> <p>22 review five thousand of those if you had to meet</p> <p>23 all the patients?</p> <p>24 A. No.</p>	<p>1 MR. HUTCHINSON: Objection,</p> <p>2 argumentative.</p> <p>3 BY MR. ANDERSON:</p> <p>4 Q. Did you need to know where the pain</p> <p>5 was in her vagina in order to come to the opinions</p> <p>6 and conclusions that you've offered in this case?</p> <p>7 A. No, not exactly because it was</p> <p>8 clinical part, clinical differential diagnosis.</p> <p>9 They found where the pain is, they excised the</p> <p>10 sling. That was their decision after examination</p> <p>11 of the patient.</p> <p>12 Q. Okay. And I'm glad you brought that</p> <p>13 up. We showed the jury earlier your diagram where</p> <p>14 you had the -- the urethra and the sling was</p> <p>15 underneath it, do you recall that?</p> <p>16 A. I do.</p> <p>17 Q. And what was the purpose of showing</p> <p>18 that to the jury?</p> <p>19 A. Just to show the relationship where</p> <p>20 the sling is and where the urethra is.</p> <p>21 Q. Okay. In the 1983 and 1984 internal</p> <p>22 Ethicon Microcrack Prolene Committee studies that</p> <p>23 you looked at are the cracks that were exhibited</p> <p>24 in those images caused by the drying?</p>

100 (Pages 394 to 397)



Vladimir Iakovlev, M.D.

Page 398	Page 400
<p>1 A. It's distracting.</p> <p>2 Q. Did you hear my question?</p> <p>3 A. Can you repeat it, because it's</p> <p>4 distracting when you flip the page</p> <p>5 Q. Can you read it back please?</p> <p>6 THE COURT REPORTER: In the 1983 and</p> <p>7 1984 internal Ethicon Microcrack polypropylene</p> <p>8 committee studies that you looked at, are the</p> <p>9 cracks that were exhibited in those images caused</p> <p>10 by the drying?</p> <p>11 THE DEPONENT: No.</p> <p>12 BY MR. ANDERSON:</p> <p>13 Q. Okay, explain.</p> <p>14 A. It was easier to see in the dry</p> <p>15 fiber because when it was wet water would be</p> <p>16 filling the cracks and it would be harder to see</p> <p>17 it. But their final conclusion was that it's not</p> <p>18 the drying which is causing the cracks.</p> <p>19 Q. Can you pull out Exhibit 1 please.</p> <p>20 That would be your general and case-specific</p> <p>21 report for the case that we're actually here for</p> <p>22 today, Ms. Ramirez.</p> <p>23 A. Yes.</p> <p>24 Q. Did counsel for Ethicon show you a</p>	<p>1 Q. And on figure 21 what does that say</p> <p>2 under the figure there?</p> <p>3 A. Examples of foreign body</p> <p>4 inflammatory reaction.</p> <p>5 Q. Did you state in this report that</p> <p>6 that was Ms. Ramirez?</p> <p>7 A. No.</p> <p>8 Q. Look at page 22. Did you state</p> <p>9 anywhere on here that this was from Ms. Ramirez's</p> <p>10 body?</p> <p>11 A. No, I didn't.</p> <p>12 Q. And why not?</p> <p>13 A. Because it's a general part. I</p> <p>14 compile it from different patients from different</p> <p>15 manufacturers to show histological features. This</p> <p>16 is not the case specific part.</p> <p>17 Q. Okay. And in the general report on</p> <p>18 page 23 did you indicate that any of those images</p> <p>19 were from Ms. Ramirez?</p> <p>20 A. No.</p> <p>21 Q. And page 24, what does it say under</p> <p>22 the figure there?</p> <p>23 A. "Example of scar encapsulation".</p> <p>24 Q. Did you state that that was</p>
Page 399	Page 401
<p>1 single slide in the Ramirez report that changes</p> <p>2 your opinions in any way?</p> <p>3 A. No.</p> <p>4 Q. Was every slide that was labelled</p> <p>5 JR(1) through (19) in the Ramirez report actual</p> <p>6 tissue and mesh samples explanted from</p> <p>7 Ms. Ramirez?</p> <p>8 A. Yes.</p> <p>9 Q. Did counsel show you a single slide</p> <p>10 in Ms. Ramirez's report that was explanted from a</p> <p>11 woman other than Ms. Ramirez?</p> <p>12 A. No.</p> <p>13 Q. Did counsel show you a single slide</p> <p>14 in the Ramirez report that was mislabelled?</p> <p>15 A. No.</p> <p>16 Q. In the general report did you state</p> <p>17 that any of those slides were Ms. Ramirez's?</p> <p>18 A. No.</p> <p>19 Q. Let's go to page 20 in the general</p> <p>20 report. On page 20?</p> <p>21 A. Yes.</p> <p>22 Q. Did you state on this that this</p> <p>23 slide was related to Ms. Ramirez?</p> <p>24 A. No.</p>	<p>1 Ms. Ramirez's sample?</p> <p>2 A. No.</p> <p>3 Q. Is it accurate that these are</p> <p>4 examples of scar encapsulation?</p> <p>5 A. Yes, it is accurate.</p> <p>6 Q. And on 25 is it accurate this is an</p> <p>7 example of scar ingrowth?</p> <p>8 A. Yes, it is.</p> <p>9 Q. And did you state on here that this</p> <p>10 was Ms. Ramirez's in any way?</p> <p>11 A. No.</p> <p>12 Q. On page 26 where it's showing nerve</p> <p>13 branches, did you state that any of these were</p> <p>14 Ms. Ramirez's?</p> <p>15 A. No, I did not state.</p> <p>16 Q. And is this an accurate depiction of</p> <p>17 nerves embedded in scar tissue?</p> <p>18 A. It is.</p> <p>19 Q. And on page 27 did you state</p> <p>20 anywhere here that this was Ms. Ramirez's?</p> <p>21 A. No.</p> <p>22 Q. And what do you state underneath the</p> <p>23 figures?</p> <p>24 A. "Examples of nerve ingrowth."</p>

101 (Pages 398 to 401)

Vladimir Iakovlev, M.D.

Page 402	Page 404
<p>1 Q. And are those accurate that those</p> <p>2 are examples of never ingrowth?</p> <p>3 A. It is accurate.</p> <p>4 Q. And on page 29?</p> <p>5 A. Yes.</p> <p>6 Q. What does it say underneath where it</p> <p>7 says figure 4(B)?</p> <p>8 A. "Examples of nerve ingrowth."</p> <p>9 Q. Does it say that that's</p> <p>10 Ms. Ramirez's?</p> <p>11 A. No.</p> <p>12 Q. Is that an accurate depiction of</p> <p>13 nerve ingrowth seen by S100 stain?</p> <p>14 A. It is.</p> <p>15 Q. On page 31 what does it say under</p> <p>16 the diagrams?</p> <p>17 A. "Examples of vascular dilatation and</p> <p>18 edema within mesh compartments."</p> <p>19 Q. Is that an accurate example of</p> <p>20 vascular dilatation and edema within mesh</p> <p>21 compartments?</p> <p>22 A. It is.</p> <p>23 Q. And did you state anywhere that that</p> <p>24 is Ms. Ramirez's?</p>	<p>1 counsel.</p> <p>2 MR. ANDERSON: That's your cross. Cross</p> <p>3 part 2. This is my part.</p> <p>4 THE DEPONENT: He did not.</p> <p>5 BY MR. ANDERSON:</p> <p>6 Q. Thank you. Again on page 35 and 36</p> <p>7 what do you list under those images?</p> <p>8 A. "An example of blue granules</p> <p>9 retained in the degradation layer."</p> <p>10 Q. Counsel didn't point those out for</p> <p>11 the jury, did he, on your cross-examination that</p> <p>12 you just said these were examples?</p> <p>13 MR. HUTCHINSON: Objection, leading.</p> <p>14 BY MR. ANDERSON:</p> <p>15 Q. Did counsel for the defense on the</p> <p>16 cross-examination allow you to tell the jury that?</p> <p>17 A. No, he didn't.</p> <p>18 Q. On cross-examination did counsel</p> <p>19 show you anything in your images or in the text of</p> <p>20 your report that was inaccurate in any way?</p> <p>21 A. No.</p> <p>22 Q. Do you stand by all of your opinions</p> <p>23 that you've given here today and all the opinions</p> <p>24 that you've expressed in this report?</p>
Page 403	Page 405
<p>1 A. No.</p> <p>2 Q. Page 32, do you see that?</p> <p>3 A. Yes.</p> <p>4 Q. Did you state anywhere that that was</p> <p>5 Ms. Ramirez's?</p> <p>6 A. No.</p> <p>7 Q. What does it say underneath the</p> <p>8 image?</p> <p>9 A. "Examples of vascular thrombosis</p> <p>10 within mesh compartments."</p> <p>11 Q. And does it accurately depict</p> <p>12 examples of vascular thrombosis within mesh</p> <p>13 compartments?</p> <p>14 A. It is.</p> <p>15 Q. And did counsel for the defense</p> <p>16 point out any of these images to you on your</p> <p>17 cross-examination shows where you said that these</p> <p>18 are just examples of these type of features?</p> <p>19 MR. HUTCHINSON: Object to the form.</p> <p>20 I'm also going to object to the extent that it</p> <p>21 mischaracterizes the testimony. I asked him about</p> <p>22 page 20 where he says all photographs are</p> <p>23 explanted Ethicon --</p> <p>24 MR. FREESE: That was your cross,</p>	<p>1 A. I do.</p> <p>2 MR. ANDERSON: We will offer all of our</p> <p>3 exhibits into evidence and fight about the</p> <p>4 admissibility later on at this time. Otherwise</p> <p>5 I'm done for right now.</p> <p>6 MR. HUTCHINSON: We may have a re-cross.</p> <p>7 Give us just a minute.</p> <p>8 THE VIDEOGRAPHER: Going off the record</p> <p>9 at 6:15 p.m.</p> <p>10 --- Whereupon the examination was</p> <p>11 completed at 6:15 p.m.</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

102 (Pages 402 to 405)

Vladimir Iakovlev, M.D.

Page 406	Page 408
<p>1 REPORTER'S CERTIFICATE</p> <p>2</p> <p>3 I, HELEN MARTINEAU, CSR, Certified</p> <p>4 Shorthand Reporter, certify;</p> <p>5 That the foregoing proceedings were</p> <p>6 taken before me at the time and place therein set</p> <p>7 forth at which time the witness was put under oath</p> <p>8 by me;</p> <p>9 That the testimony of the witness and</p> <p>10 all objections made at the time of the examination</p> <p>11 were recorded stenographically by me and were</p> <p>12 thereafter transcribed;</p> <p>13 That the foregoing is a true and</p> <p>14 accurate transcript of my shorthand notes so</p> <p>15 taken.</p> <p>16</p> <p>17</p> <p>18</p> <p>19 PER: HELEN MARTINEAU</p> <p>20 CERTIFIED SHORTHAND REPORTER</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1</p> <p>2 ACKNOWLEDGMENT OF DEPONENT</p> <p>3</p> <p>4 I, _____, do</p> <p>5 hereby certify that I have read the</p> <p>6 foregoing pages, and that the same is</p> <p>7 a correct transcription of the answers</p> <p>8 given by me to the questions therein</p> <p>9 propounded, except for the corrections or</p> <p>10 changes in form or substance, if any,</p> <p>11 noted in the attached Errata Sheet.</p> <p>12</p> <p>13</p> <p>14</p> <p>15 VLADIMIR IAKOVLEV, MD DATE</p> <p>16</p> <p>17</p> <p>18 Subscribed and sworn</p> <p>19 to before me this</p> <p>20 _____ day of _____, 20____.</p> <p>21 My commission expires: _____</p> <p>22</p> <p>23</p> <p>24</p> <p>22 Notary Public</p>
Page 407	
<p>1 - - - - -</p> <p>2 E R R A T A</p> <p>3 - - - - -</p> <p>4 PAGE LINE CHANGE</p> <p>5</p> <p>6 REASON: _____</p> <p>7</p> <p>8 REASON: _____</p> <p>9</p> <p>10 REASON: _____</p> <p>11</p> <p>12 REASON: _____</p> <p>13</p> <p>14 REASON: _____</p> <p>15</p> <p>16 REASON: _____</p> <p>17</p> <p>18 REASON: _____</p> <p>19</p> <p>20 REASON: _____</p> <p>21</p> <p>22 REASON: _____</p> <p>23</p> <p>24 REASON: _____</p>	

103 (Pages 406 to 408)